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Industry News

Cassiopea announces FDA acceptance of its new drug application for clascoterone cream 1%, the first new mechanism of action for acne in nearly 40 years. Cassiopea, Press Release. November 08, 2019.

<https://www.cassiopea.com/2019/11/08/cassiopea-announces-fda-submission-of-new-drug-application-for-clascoterone-cream-1-the-first-new-mechanism-of-action-for-acne-in-nearly-40-years-2/>

Cassiopea SpA (SIX: SKIN), a specialty pharmaceutical company developing and commercializing prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, announced today the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for clascoterone cream 1%. Cassiopea is seeking marketing approval for clascoterone cream 1% for the treatment of acne. The FDA has set August 27, 2020 as the Prescription Drug User Fee Act (PDUFA) action date. Clascoterone, a new chemical entity, is a proposed first-in-class topical androgen receptor inhibitor under FDA review for the treatment of acne (in a 1% cream) and in late stage development for the treatment of androgenetic alopecia (in a higher strength solution) in males. Although clascoterone's exact mechanism of action is unknown, laboratory studies suggest clascoterone competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles. Because of clascoterone's likely local effect at the site of application, the risk of off-target, or systemic side effects, is minimized. Clascoterone cream 1% targets androgen receptors at the site of application, inhibiting the local (skin) effects of DHT a key driver of acne lesion development. Laboratory studies show that clascoterone inhibits lipid production from cultured oil producing cells (sebocytes) and reduces proinflammatory cytokines, mediators influenced by androgens. Thus, pathways that foster acne lesion development appear to be disrupted by clascoterone at the site of application. Unlike oral hormonal therapies for acne, it may potentially be used in both male and female patients. Last year, Cassiopea announced topline results from two pivotal phase III clinical trials for clascoterone cream 1%, demonstrating highly statistically significant improvements for all primary clinical endpoints. No treatment-related serious adverse events among patients were recorded during the trials; local skin reactions, if present, were similar to vehicle and predominantly classified as mild. Safety results, announced earlier this year, were confirmed in an open-label safety study for a treatment period of up to one year, with an expanded drug application surface area that included both the face and trunk. The extended duration and coverage of the topically applied drug did not increase the incidence of significant side effects. "We look forward to working closely with FDA during the review process. If approved, clascoterone cream 1% will be the first new mechanism of action in the treatment of acne in nearly 40 years, offering dermatologists and patients a new and effective therapeutic alternative," said Diana Harbort, CEO of Cassiopea. She added, "We are committed to finding a way to treat acne that addresses the root causes of the condition."

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New Medical Research

Acne fulminans and cutibacterium acnes phylotypes. Bocquet-Trémoureaux S, Corvec S, Khammari A, et al. J Eur Acad Dermatol Venereol. 2019 Nov 12. doi: 10.1111/jdv.16064. [Epub ahead of print]

<https://www.ncbi.nlm.nih.gov/pubmed/31715640>

Background: Acne fulminans (AF) is a rare and severe form of inflammatory acne. It is characterized by a sudden worsening of acne with appearance of ulcero-necrotic lesions, which can be associated with systemic signs. Its pathophysiology and the best therapeutic strategy are only partially known. Objective: Our main objectives were to

describe the clinical and biological profile of AF patients and to determine whether there was a difference in *C. acnes* phylotype in AF compared to acne vulgaris. The secondary objective was to assess the efficacy of different therapies. Methods: A retrospective observational study was conducted in all patients followed for AF in our department between 2008 and 2018. Bacteriological samples were taken from each patient to analyze *C. acnes* phylotype distribution. The therapeutic response was assessed using the ECLA and GEA scales. Results: Fifteen patients with a median age of 15 years were included (12 men, 80%). A family history of acne was found in 86.7% of patients. Nine patients (60%) had isotretinoin-induced AF. Only one patient (6.7%) showed systemic signs. The bacteriological culture was positive for *C. acnes* in 80% of patients. The predominant phylotype was IA1 in 60% of patients, corresponding to the predominant phylotype in acne vulgaris. Only 33.3% of patients were in remission after a first-line treatment with systemic corticosteroids, alone or in combination. Seven patients were treated with biotherapy, including 5 successfully with secukinumab. Conclusion: Our results suggest that there is no specific *C. acnes* phylotype associated with AF, raising the hypothesis that acute inflammation associated with AF may be more related to an abnormal cutaneous innate immunity activation. The use of preventive strategies, the impact of combined treatments and an assessment of the role of biotherapies, especially anti-IL-17, in AF treatment remain to be more investigated.

Evaluation of the safety and efficacy of a picosecond alexandrite laser with DLA for acne scars in Chinese patients. Zhang M, Fang J, Wu Q, Lin T. *Lasers Surg Med.* 2019 Nov 10. doi: 10.1002/lsm.23177. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31709575>

Background and objectives: Recently, picosecond laser treatment has been used as an effective treatment for acne scars. To evaluate the efficacy and safety of a picosecond alexandrite laser with a diffractive lens array in the treatment of acne scars in Chinese patients. Study design/materials and methods: Patients with facial acne scars were treated with a picosecond alexandrite laser in three sessions at 4- to 6-week intervals and followed up for 2 months. Primary outcomes were measured by physicians' blinded evaluation of the acne scar using the ECCA (échelle d'éva physicians'luation clinique des cicatrices d'acné) grading scale. The secondary outcomes included the investigator global assessment (IGA) on the improvement of post-inflammatory erythema (PIE), patients' assessment of improvement on a 4-point scale and of satisfaction on a 5-point scale. Pain scores and adverse effects were also evaluated. Result: Twenty patients with Fitzpatrick skin types III and IV were enrolled in the study and completed all treatment and follow-up visits. The mean ECCA scores fell from 197.75 ± 35.26 to 142.00 ± 35.92 (a 28% improvement), and the change was significant ($P = 0.000$). The mean IGA score of PIE improvement was 3.03 ± 0.75 (0 = no improvement and 4 = 76-100% improvement). On the basis of the patients' self-assessment, the average improvement scores were 2.30 ± 0.98 (0 indicating 0-25% improvement and 3 indicating >75% improvement). In total, 50% and 30% of the patients were "satisfied" and "very satisfied," respectively, with the treatment. The mean pain score was 3.20 ± 0.50 (0 = no pain, 10 = maximum pain) with topical anesthesia. The adverse effects included transient and mild erythema, edema, and scabbing. Conclusions: Treatment with a picosecond alexandrite laser with a diffractive lens array is effective and safe for acne scars in Chinese patients.

Treatment of erythematotelangiectatic rosacea with pulsed-dye laser and oxymetazoline 1.0% cream: A retrospective study. Suggs AK, Macri A, Richmond H, et al. *Lasers Surg Med.* 2019 Nov 10. doi: 10.1002/lsm.23176. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31709571>

Background and objectives: Pulsed-dye laser (PDL) and oxymetazoline 1.0% cream are each used for the treatment of erythematotelangiectatic (ET) rosacea. PDL targets oxyhemoglobin and can reduce facial erythema and telangiectasias. Oxymetazoline 1.0% cream is an α adrenergic agonist, which has shown to reduce facial erythema.

The aim of this study was to determine the degree of erythema improvement and telangiectasia clearance after combination treatment with PDL plus oxymetazoline 1.0% cream. Study design/materials and methods: This retrospective study was conducted at two sites. Pre- and post-treatment cross-polarized images from subjects on combination treatment with PDL and oxymetazoline 1.0% cream were graded by a board-certified dermatologist at each practice. Blinded images were analyzed using the Clinical Erythema Assessment (CEA) Scale (0 = clear and 4 = severe). Unblinded images were analyzed using the five-point Telangiectasia Scale to determine the degree of improvement post-treatment compared with baseline (1 = <5% clearance and 5 = 75-100% clearance). Results: Thirty-one subjects (20 females, 11 males) of age 51 ± 13 years (mean \pm standard deviation) were included in the study after an average of 4 months (range: 1-13) of daily oxymetazoline 1.0% cream and two (range: 1-4) PDL treatments. At baseline, 87% of subjects had CEA Grade 2 (mild erythema) or higher. For erythema, 55% of subjects improved by at least one CEA grade and 13% achieved two grades of improvement post-treatment. For telangiectasias, 90% of subjects achieved at least a two-point clearance (5-25%), 62% at least a three-point clearance (25-50%), and 41% at least a four-point clearance (50-75%) post-treatment. Compared with subjects with baseline CEA Grade 1-2 (almost clear to mild erythema), significantly more subjects with baseline CEA Grade 3-4 (moderate to severe erythema) achieved at least one CEA grade of improvement ($P = 0.021$) and two grades of CEA improvement ($P = 0.041$). A higher percentage of baseline CEA Grade 3-4 subjects achieved at least a two-point clearance in telangiectasias ($P = 0.055$). Conclusions: Combination treatment with PDL and daily oxymetazoline 1.0% cream can safely and effectively reduce erythema and telangiectasias. Limitations include the retrospective design of the study, small sample size, and lack of a control group.

Impact of nanostructured lipid carriers on dapson delivery to the skin; In vitro and in vivo studies. Elmowafy M, Shalaby K, Ali HM, et al. *Int J Pharm.* 2019 Nov 9:118781. doi: 10.1016/j.ijpharm.2019.118781. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31715347>

The main objective of this study was to develop, characterize and evaluate the potential use of dapson-loaded nanostructured lipid carriers (NLCs) as a topical treatment for acne. Differently charged NLC formulations were successfully prepared using an emulsification/sonication method. The particle sizes ranged from 106.2 ± 5.6 nm to 151.3 ± 7.4 nm, and the NLCs possessed the predicted surface charges, depending on the emulsifier used (Tween 80, Transcutol P, or cetyltrimethylammonium bromide). The entrapment efficiencies ranged from 76.5 ± 3.8 % to 91.1 ± 3.9 %. Selected formulations were assessed for possible interactions, in vitro release, ex vivo skin permeation, pharmacological efficacy and safety compared with a hydroalcoholic solution. Dapson was embedded in the lipid matrix of NLCs and behaved as controlled release system with a good occlusive effect. Dapson-loaded cationic NLC formulation enhanced the skin permeation of dapson, increase the amount of dapson retained in the skin in controlled manner, and improved the anti-rosacea activity. Based on these encouraging results, cationic NLC represents a promising carrier for the safe topical delivery of dapson.

Use of a monofilament debridement pad in the treatment of acne vulgaris. Eberlein T, Wiegand C, Andriessen A, et al. *J Wound Care.* 2019 Nov 2;28(11):780-783. doi: 10.12968/jowc.2019.28.11.780. <https://www.ncbi.nlm.nih.gov/pubmed/31721661>

Objective: Acne vulgaris (acne) presents with increased oil-sebum secretion and subsequent formation of comedones, papules, pustules and nodules. Skin cleansing is part of the daily routine to improve skin condition. A monofilament debridement pad has shown to be effective when used for wound debridement and skin cleansing in dermatological conditions. The pad may offer benefits when used for acne affected skin. Methods: The in vitro

cleansing capacity of the monofilament fibre pad was analysed and compared with commercially available cosmetic pads. For this purpose, a sebum model consisting of glass plates coated with an oil-red-stained layer of artificial sebum was used. To gain clinical experience a case series evaluated cleansing efficacy of the monofilament debridement pad in combination with polyhexanide and sodium-hypochlorite based solutions. Over a period of four months, seven individuals suffering from retentive moderate facial acne who visited the dermatology clinic for their acne used the pad as necessary, ranging from twice weekly to daily, dependent on the sensitivity of the patient's skin condition. Results: The in vitro study exhibited a significantly better cleansing efficacy of the monofilament debridement pad compared with the cosmetic pads. After single use of the pad subject scores on sebum reduction revealed excellent/very good in 42.9% and acceptable in 57.1% of cases. After repeated use of the monofilament pads scores on sebum reduction of excellent/very good were given in 85.7% and acceptable in 14.3% of cases. Subject scored handling of the pad and comfort during use also received favourable ratings. Conclusion: These initial results show the potential of the monofilament debridement pad for cleansing of acne-prone and acne affected skin. More robust studies are needed to confirm these results.

Establishment of an anti-acne vulgaris evaluation method based on TLR2 and TLR4-mediated interleukin-8 production. Suvanprakorn P, Tongyen T, Prakhongcheep O3, et al. *In Vivo*. 2019 Nov-Dec;33(6):1929-1934. doi: 10.21873/invivo.11687. <https://www.ncbi.nlm.nih.gov/pubmed/31662521>

Background/aim: To date, no cell-based assay that focuses on the prime cause of acne initiation through activation of toll-like receptor2 and 4 and interleukin-8 (IL-8) production exists. Herein, we present an assay that evaluates acne by determining TLR2 and 4 expression and activation. Materials and methods: Viability of keratinocytes was determined by the MTT assay. IL-8 was evaluated by ELISA. Immunocytochemistry was performed for determining receptor expression. Results: Lipoteichoic acid (LTA), peptidoglycan (PGN) and lipopolysaccharide (LPS) induced IL-8 production. Pre-treatment of cells with TLR2 and TLR4 inhibitors, before stimulation, reduced IL-8 production. Zinc gluconate was used for verification. Zinc can significantly suppress IL-8 production in the system. Treatment of cells with LTA+PGN or LPS resulted in increased TLR2 and TLR4 expression on the cell surface. This effect was prevented by zinc treatment. Conclusion: The measurement of IL-8 and TLR2 and TLR4 levels can be used for the evaluation of anti-acne treatment.

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Prevalence and psychological impact of acne vulgaris in female undergraduate medical students of Rawalpindi and Islamabad, Pakistan. Babar O, Mobeen A. *Cureus*. 2019 Sep 22;11(9):e5722. doi: 10.7759/cureus.5722. <https://www.ncbi.nlm.nih.gov/pubmed/31720190>

Acne vulgaris is a common skin disease, affecting approximately 9.4% of the world's population, with considerable effect on the quality of life. According to a previously conducted study, the prevalence rate of acne in Pakistan was found to be 5%. And to this date, no reliable data is available about the prevalence of acne in Rawalpindi and Islamabad, Pakistan. Objectives To determine the prevalence of acne vulgaris and its psycho-social impact on female undergraduate medical students of Rawalpindi and Islamabad. Methods A cross-sectional study was conducted during the month of August 2019 among female undergraduate medical students from three randomly selected medical colleges of Rawalpindi and Islamabad. The diagnosed cases of acne vulgaris were assessed by using the Dermatology Life Quality Index (DLQI). The collected data were then analyzed using SPSS version 20 (IBM Corp., Armonk, NY, US). Results The prevalence of acne vulgaris was found to be 14.47% in female undergraduate medical

students of Rawalpindi and Islamabad. Sixty percent (n=99) were found to have itchy sores and stinging skin, 66.7% (n=110) were embarrassed by their acne-prone skin, and the social activity of 60% (n=99) of the participants was affected by their active acne. Of the students, 73.9% were not affected by their acne while studying or working. Around 61.2% (n=101) complained that their acne treatment was a problem and hiding it took time or made a mess. Two percent showed a severe impact, with 14% having very large, 44% moderate, 30% low, and the remaining 10% with no effect of acne in their psychosocial functioning. Conclusion Acne vulgaris is a chronic skin disease that considerably affects the psychosocial functioning of female undergraduate medical students. A holistic approach in treating acne requires the participation of a dermatologist and mental health professional.

Clinical Reviews

Serum IL-36 α , IL-36 β , and IL-36 γ levels in patients with hidradenitis suppurativa: Association with disease characteristics, smoking, obesity, and metabolic syndrome. Hayran Y, Allı N, Yücel Ç, et al. Arch Dermatol Res. 2019 Nov 13. doi: 10.1007/s00403-019-02012-w. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31722038>

Hidradenitis Suppurativa (HS) is a chronic, inflammatory, and relapsing skin disease. Pathogenesis of the disease is not well understood, but many studies revealed the potential role of cytokines and interleukins. IL-36 expression was increased in tissue samples of HS patients with conflicting result regarding serum levels. To investigate serum IL-36 levels in HS patients and evaluate their relation to disease characteristics, 44 patients diagnosed with HS and 44 age and sex-matched healthy controls were included in the study. Enzyme-linked immunosorbent assay (ELISA) was used to measure serum IL-36 concentrations. Serum levels of IL-36 α , IL-36 β , and IL-36 γ were significantly elevated in HS patients compared to healthy controls (all three $p < 0.001$). IL-36 α , IL-36 β , and IL-36 γ levels were significantly higher in current smokers compared to non-smokers and positively correlated with number of packs/year ($p = 0.002$, $r = 0.402$; $p = 0.042$, $r = 0.242$ and $p = 0.001$, $r = 0.391$, respectively). IL-36 α , IL-36 β , and IL-36 γ levels were also elevated in obese patients and patients with metabolic syndrome ($p = 0.007$, < 0.001 , 0.038 , 0.004 , 0.006 , and 0.048 , respectively). After stratified and restricted analyses for smoking, obesity, and metabolic syndrome IL-36 α , IL-36 β , and IL-36 γ increased the risk of HS 11.0, 1.79, and 4.5 time, respectively (95% CI 1.7-71.28, $p < 0.001$; 95% CI 1.04-3.06, $p = 0.005$ and, 95% CI 1.007-20.106, $p = 0.040$, respectively). Elevated serum IL-36 levels may contribute to pathogenesis of HS and may be a candidate for future biological treatment of the disease.

Acne from the young patient's perspective. Claudel JP, Auffret N, Leccia MT, et al. J Eur Acad Dermatol Venereol. 2019 Nov 12. doi: 10.1111/jdv.16067. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31715036>

Acne may significantly impact quality of life (QOL), self-esteem and self-worth. The aim of this paper was to provide an overview of the knowledge and perception of acne and its risk factors in adolescents and young adults. The most critical issues reported for an optimal management of this specific population were identified. A PubMed literature review of results from patient-oriented surveys published between 2007 and 2018 was conducted. Two different types of survey were used: those using either validated questionnaires or specifically developed questionnaires. No consistency or directly comparable data with regards to age, onset, duration, severity and treatment of acne and by whom and where data were collected were observed. Acne affected female patients psychologically more than male patients. The majority referred to their treating physician in order to obtain information and all surveys pointed out that specific treatment programs would allow to increase awareness about acne. Beliefs, traditions and economic factors continue to impact the perception of and treatment choices for acne in almost all countries and cultures, maintaining

the improvement of awareness about acne a major global health challenge. In conclusion, identifying, considering and managing the patient's concerns about acne may improve the young patient's well-being and thus decrease additional health-care expenses for emerging psychological comorbidities. This can be achieved by creating substantial and structured awareness through local and global information campaigns via the treating physicians, internet, social networks and education.

Trifarotene: First approval. Scott LJ. *Drugs*. 2019 Nov 12. doi: 10.1007/s40265-019-01218-6. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31713811>

Topical trifarotene (Aklief®) is a first-in-class, fourth-generation retinoid [selective retinoic acid receptor (RAR)- γ agonist] being developed by Galderma Research and Development LLC for the treatment of acne vulgaris. In October 2019 trifarotene received its first global approval in the USA for the topical treatment of acne vulgaris in patients 9 years of age and older. This article summarizes the milestones in the development of trifarotene leading to its first global approval for acne vulgaris.

The skin and gut microbiome and its role in common dermatologic conditions. Ellis SR, Nguyen M, Vaughn AR, et al. *Microorganisms*. 2019 Nov 11;7(11). pii: E550. doi: 10.3390/microorganisms7110550. <https://www.ncbi.nlm.nih.gov/pubmed/31717915>

Microorganisms inhabit various areas of the body, including the gut and skin, and are important in maintaining homeostasis. Changes to the normal microflora due to genetic or environmental factors can contribute to the development of various disease states. In this review, we will discuss the relationship between the gut and skin microbiome and various dermatological diseases including acne, psoriasis, rosacea, and atopic dermatitis. In addition, we will discuss the impact of treatment on the microbiome and the role of probiotics.

Acne vulgaris: A patient and physician's experience. Espinosa NI, Cohen PR. *Dermatol Ther (Heidelb)*. 2019 Nov 7. doi: 10.1007/s13555-019-00335-0. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31701473>

In this article, the first coauthor, a young woman with acne vulgaris, shares her experience with the condition; she not only describes the clinical presentation and the eventual successful treatment of her acne, but also the emotional consequences that this skin disorder caused. The second coauthor, the patient's dermatologist, reviews some of the features of acne vulgaris: morphologic manifestations, pathogenesis, and treatment options. He also summarizes the patient's response to isotretinoin therapy. In addition, he reveals his subsequent enlightenment regarding the acne-related non-dermatologic effects that the patient experienced and the significant improvement of her self-image that occurred following the successful treatment of her acne.

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Young people's perceptions of acne and acne treatments: Secondary analysis of qualitative interview data. Ip A, Muller I, Geraghty AWA, et al. *Br J Dermatol*. 2019 Nov 7. doi: 10.1111/bjd.18684. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31701523>

Background: Acne vulgaris is a common skin condition affecting approximately 95% of adolescents to some extent. First line treatments are topical preparations but non-adherence is common. A substantial proportion of patients take long courses of oral antibiotics, associated with antibiotic resistance. This study aimed to explore young people's views and experiences of acne and its treatments. Methods: We report a secondary thematic analysis of interview data collected by researchers in HERG, University of Oxford. A total of 25 transcripts from young people aged 13-24

years with acne were included. Results: Acne is often perceived as a short-term self-limiting condition of adolescence and this appears to have implications for seeking treatment or advice. Participants widely perceived topical treatments as being ineffective, which seemed related to unrealistic expectations around speed of onset of action. Many participants felt they had tried all available topical treatments, although were unsure what was in them or unaware of differences between cosmetic and pharmaceutical treatments. They had concerns around how to use topicals 'properly' and how to avoid side effects. They were also concerned about side effects or necessity of oral treatments, though few seemed aware of antibiotic resistance. Conclusion: People with acne need support to manage their condition effectively, particularly a better understanding of different topicals, how to use them and how to avoid side effects. Unrealistic expectations about the onset of action of treatments appears to be a common cause of frustration and non-adherence. Directing people towards accessible evidence-based information is crucial.

Demographic and clinical features of hidradenitis suppurativa in Turkey. Yüksel M, Basım P. *J Cutan Med Surg.* 2019 Nov 7:1203475419887732. doi: 10.1177/1203475419887732. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31698918>

Background: The literature contains conflicting reports on the epidemiology and frequency of hidradenitis suppurativa (HS), a chronic, recurrent inflammatory disease of the apocrine glands. Objective: To evaluate the clinical and demographic characteristics of HS cases in Turkey and investigate the similarities with world epidemiology. Method: The records of 208 patients that presented to our polyclinics and were diagnosed with HS between June 2012 and July 2017 were retrospectively evaluated. Results: Of the cases, 68.3% were male and 31.7% were female. Of the patients, 75.5% had no family history of HS, 60.6% were smokers, 39.4% were aged 20-29 years, and 36.1% were aged 30-39 years. The most commonly involved regions were the axilla (62%), groin (50.5%), and gluteus (15.9%). According to univariate analyses, male patients had higher disease stages than females (odds ratio=1.67). The patients with groin involvement, high body mass index (BMI), and low education level (0-8 years) had higher risk of severe disease stage (odds ratio=1.63, 8.91, and 1.51, respectively). The most commonly used treatment was oral antibiotics in Hurley stages I and II, and surgical intervention in Hurley III. In all 3 Hurley stages, clavulanic acid-amoxicillin combination was the mostly used systemic antibiotic (41.8%, 43.2%, and 47.8%, respectively). Conclusions: This is the first epidemiological study on HS in the Turkish population, where HS shows male predominance. Male gender, low education level, absence of acne, high BMI, and groin involvement were associated with severe disease stages. Determining associated comorbidities and possible risk factors is important in progression and prevention of the disease.

Prevalence and impact of dietary avoidance among individuals with hidradenitis suppurativa. Dempsey A, Butt M, Kirby JS. *Dermatology.* 2019 Nov 1:1-7. doi: 10.1159/000503063. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31678977>

Background: People with hidradenitis suppurativa (HS) are interested in dietary alterations to manage the condition. However, there are few data on the prevalence of this or the impact on HS activity. The objective of this study was to investigate the prevalence and impact of dietary alterations made by people with HS. Methods: A cross-sectional survey was sent to people with HS through multiple sources. Participants reported food alterations in the prior 6 months. -Results: Overall, 242 complete surveys were included in this analysis; the mean age was 35.8 years, and most (87.5%) were women. The majority (75.8%, n = 182) altered at least one food from their diet. Within this group, 154 (84.6%) made changes to multiple food groups. The top 5 food groups that were altered were gluten (48.8%), dairy (44.2%), refined sugars (40.0%), tomatoes (36.7%), and alcohol (37.1%). Smoking was eliminated in 27.5% of participants. Some participants (30.9%) reported the change made the HS "much better." Conclusions: Dietary

alteration to manage HS was common among participants in this study. Some people reported improvement in HS activity, but some noted worsening. Additional research is needed to evaluate the efficacy of dietary alteration to manage HS and to better understand the underlying pathomechanisms.

Blue-light therapy for acne vulgaris: A systematic review and meta-analysis. Scott AM, Stehlik 2, Clark J, et al. *Ann Fam Med.* 2019 Nov;17(6):545-553. doi: 10.1370/afm.2445. <https://www.ncbi.nlm.nih.gov/pubmed/31712293>
 Purpose: Antibiotic use in acne treatment raises concerns about increased resistance, necessitating alternatives. We assessed the effectiveness of blue-light therapy for acne. Methods: We analyzed randomized controlled trials comparing blue light with nonlight interventions. Studies included people of any age, sex, and acne severity, in any setting, and reported on investigator-assessed change in acne severity, patients' assessment of improvement, change in inflammatory or noninflammatory lesions, and adverse events. Where data were sufficient, mean differences were calculated. Results: Eighteen references (14 trials) including 698 participants were included. Most of the trials were small and short (<12 weeks) and had high risk of bias. Investigator-assessed improvement was quantitatively reported in 5 trials, of which 3 reported significantly greater improvement in blue light than comparator, and 2 reported improvement. Patients' assessments of improvement were quantitatively reported by 2 trials, favoring blue light. Mean difference in the mean number of noninflammatory lesions was nonsignificant between groups at weeks 4, 8, and 10-12 and overall (mean difference [MD] = 3.47; 95% CI, -0.76 to 7.71; P = 0.11). Mean difference in the mean number of inflammatory lesions was likewise nonsignificant between groups at any of the time points and overall (MD = 0.16; 95% CI, -0.99 to 1.31; P = 0.78). Adverse events were generally mild and favored blue light or did not significantly differ between groups. Conclusion: Methodological and reporting limitations of existing evidence limit conclusions about the effectiveness of blue light for acne. Clinicians and patients should therefore consider the balance between its benefits and adverse events, as well as costs.

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Skin changes in the obese patient. Hirt PA, Castillo DE, Yosipovitch G, Keri JE. *J Am Acad Dermatol.* 2019 Nov;81(5):1037-1057. doi: 10.1016/j.jaad.2018.12.070. <https://www.ncbi.nlm.nih.gov/pubmed/31610857>
 Obesity is a worldwide major public health problem with an alarmingly increasing prevalence over the past 2 decades. The consequences of obesity in the skin are underestimated. In this paper, we review the effect of obesity on the skin, including how increased body mass index affects skin physiology, skin barrier, collagen structure, and wound healing. Obesity also affects sebaceous and sweat glands and causes circulatory and lymphatic changes. Common skin manifestations related to obesity include acanthosis nigricans, acrochordons, keratosis pilaris, striae distensae, cellulite, and plantar hyperkeratosis. Obesity has metabolic effects, such as causing hyperandrogenism and gout, which in turn are associated with cutaneous manifestations. Furthermore, obesity is associated with an increased incidence of bacterial and Candida skin infections, as well as onychomycosis, inflammatory skin diseases, and chronic dermatoses like hidradenitis suppurativa, psoriasis, and rosacea. The association between atopic dermatitis and obesity and the increased risk of skin cancer among obese patients is debatable. Obesity is also related to rare skin conditions and to premature hair graying. As physicians, understanding these clinical signs and the underlying systemic disorders will facilitate earlier diagnoses for better treatment and avoidance of sequelae.

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Incorporation of benzoyl peroxide nanocrystals into adapalene-loaded solid lipid microparticles: Part II - solid-in-oil dispersion of nanoparticulate benzoyl peroxide. Brammann C, Müller-Goymann CC. *Int J Pharm.* 2019 Oct 29;118792. doi: 10.1016/j.ijpharm.2019.118792. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31676340>

Benzoyl peroxide as a monotherapeutic and in combination with adapalene is a cornerstone of current acne therapy, but its unfavourable side effect profile reduces the therapeutic value of this compound. The incorporation into an adapalene-loaded microparticulate lipid matrix, which - via the principle of targeted erosion - allows the targeted release of active substances in the hair follicles, is a promising approach to reduce side effects such as skin redness, increased scaling and allergic reactions. However, there are challenges to the production of such a vehicle which require a galenic solution. That is in particular the redispersion of nanoparticulate benzoyl peroxide in lipids while maintaining its nanodisperse character. In the present work, the lamellar liquid crystalline phase of a binary water/phospholipid system is used to stabilize a nanosuspension during freeze-drying. Both after redispersing in water and after dispersing in nonpolar fat phases, the initial size of the nanosuspension was recovered with only minor deviations. The found cryoprotective effect of purified phospholipid allows the generation of highly concentrated solid-in-oil systems both in fat phases liquid at room temperature and in lipid melts, which after solidification can serve as starting material for the preparation of lipid microparticles loaded with benzoyl peroxide nanocrystals.

Sarecycline hydrochloride for the treatment of acne vulgaris. Kaul G, Saxena D, Dasgupta A, Chopra S. *Drugs Today (Barc).* 2019 Oct;55(10):615-625. doi: 10.1358/dot.2019.55.10.3045040.

<https://www.ncbi.nlm.nih.gov/pubmed/31720559>

Sarecycline hydrochloride (Seysara) is a novel, narrow-spectrum tetracycline derivative approved by the U.S. Food and Drug Administration (FDA) in October 2018 for the treatment of inflammatory non-nodular moderate to severe acne vulgaris. It was initially developed by Paratek Pharmaceuticals, Inc. (U.S.) and Allergan plc (U.S.), which later was acquired by Ammirall S.A. (Barcelona, Spain). Ammirall S.A. obtained U.S. FDA approval of oral sarecycline tablets under the trade name Seysara. Sarecycline exhibits antibacterial activity against important skin/soft tissue pathogens with targeted activity against *Cutibacterium acnes*--an anaerobic Gram-positive bacterium linked with acne lesions--and also exerts anti-inflammatory effects as do other tetracyclines used in the treatment of acne vulgaris. Interestingly, unlike the broad-spectrum tetracyclines, sarecycline is less potent against aerobic Gram-negative bacilli and anaerobic bacteria associated with endogenous intestinal microbial flora. This provides it with a more specific antibacterial spectra with lower chances of adverse off-target antibacterial effects, thus making it a promising choice of treatment over others in its class. It has also demonstrated low propensity to resistance as compared with other tetracyclines and is also active against tetracycline-resistant *Staphylococcus aureus* as well as erythromycin- and clindamycin-resistant *C. acnes* strains. Sarecycline has successfully undergone numerous phase I, phase II and three phase III studies establishing it as a well-tolerated once-daily oral drug available as a tablet for the treatment of patients 9 years of age or above.

Treatment of Demodex-associated inflammatory skin conditions: A systematic review. Jacob S, VanDaele MA, Brown JN. *Dermatol Ther.* 2019 Oct 3:e13103. doi: 10.1111/dth.13103. [Epub ahead of print] <https://www.ncbi.nlm.nih.gov/pubmed/31583801>

Bacterial folliculitis, rosacea, and other common skin conditions have been linked to infestation by Demodex mites (human demodicosis). Currently, there is little guidance for treatment of inflammatory conditions associated with demodicosis. Thus, the objective of this review is to evaluate the efficacy and safety of treatments utilized for Demodex infestation. PubMed (1946 to January 2019) and Embase (1947 to January 2019) were searched with the following

term combinations: Demodex mites, Demodex folliculitis, demodicosis, Demodex folliculorum, or Demodex brevis and articles evaluating treatment of body surface colonization with Demodex mites were included. Common interventions used for Demodex infestation include metronidazole-based therapies, permethrin, benzoyl benzoate, crotamiton, lindane, and sulfur. Short courses of metronidazole taken orally have shown efficacy in reducing Demodex density. Additionally, topical administration of permethrin daily or twice daily was shown to be efficacious across multiple studies. Crotamiton and benzyl benzoate were also efficacious treatments. Several therapies were associated with mild-to-moderate skin irritation. Due to limited data, no standard of care can be identified at this time. Efficacious treatment options may include permethrin, crotamiton, benzyl benzoate, and oral metronidazole; however, long-term efficacy has not been established.

Association of rosacea with inflammatory bowel disease: A MOOSE-compliant meta-analysis. Wang FY, Chi CC. *Medicine* (Baltimore). 2019 Oct;98(41):e16448. doi: 10.1097/MD.00000000000016448. <https://www.ncbi.nlm.nih.gov/pubmed/31593075>

Rosacea has been reported with several systemic comorbidities, but its relationship with inflammatory bowel disease (IBD) is unclear. Thus, our objective is to conduct a meta-analysis on the association of rosacea with IBD. We conducted a meta-analysis and searched MEDLINE, CENTRAL, and Embase databases for case-controlled and cohort studies that assessed the association of rosacea with IBD from inception to July 2nd, 2018. Two authors independently selected studies, extracted data, and assessed the risk of bias of included studies. Disagreement was resolved by discussion. We performed random-effects model meta-analysis to obtain the pooled risk estimates for Crohn disease (CD) and ulcerative colitis (UC) in patients with rosacea. We included three case-control and three cohort studies. The risk of bias of included studies was generally low. The meta-analysis on case-control studies showed marginally increased odds of CD (pooled odds ratio (OR) 1.30, 95% confidence interval (CI) 0.99-1.69) and a significantly increased odds of UC (pooled OR 1.64, 95% CI 1.43-1.89) in patients with rosacea. The meta-analysis on cohort studies demonstrated significant increased risk of CD (pooled hazard ratio (HR) 1.58, 95% CI 1.14-2.20) and UC (pooled HR 1.18, 95% CI 1.01-1.37) in patients with rosacea. The evidence indicates an association of rosacea with IBD. If patients with rosacea suffer from prolonged abdominal pain, diarrhea, and bloody stool, referral to gastroenterologists may be considered.

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Skin disease related to metabolic syndrome in women. Misitzis A, Cunha PR, Kroumpouzou G. *Int J Womens Dermatol*. 2019 Jul 4;5(4):205-212. doi: 10.1016/j.ijwd.2019.06.030. eCollection 2019 Sep. <https://www.ncbi.nlm.nih.gov/pubmed/31700973>

Sex hormones are involved in pathways of metabolic syndrome (MetS), an observation supported by animal studies. The relationships of sex hormones with components of MetS, such as insulin resistance and dyslipidemia, have been studied in pre- and postmenopausal women. High testosterone, low sex hormone-binding globulin, and low estrogen levels increase the risks of MetS and type 2 diabetes in women. Cutaneous diseases that are sex hormone mediated, such as polycystic ovary syndrome, acanthosis nigricans, acne vulgaris, and pattern alopecia, have been associated with insulin resistance and increased risk for MetS. Furthermore, inflammatory skin conditions, such as hidradenitis suppurativa and psoriasis, increase the risk for MetS. Patients with such skin conditions should be followed for metabolic complications, and early lifestyle interventions toward these populations may be warranted.

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