AARS HOT TOPICS MEMBER NEWSLETTER

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Industry News

Accutane Appeal Prompts Calls for NJ Court to Adopt 'Daubert' [cid:image001.jpg@01D389FF.92B41EA0] January 18, 2018. Tannen Maury/ Bloomberg News.

An appeal before the New Jersey Supreme Court over expert testimony in suits concerning the acne drug Accutane is seen by many as a chance to revise the state's standard for admitting such evidence. Lawyers for drugmaker Hoffmann-La Roche have asked the court to consider whether a trial judge exceeded his authority by excluding two expert witnesses for the plaintiffs based on a conclusion that their views lacked support in the scientific community. That decision was later overturned by<http://law.justia.com/cases/new-jersey/appellate-division-published/2017/a4698-14.html the Appellate Division http://www.njlawjournal.com/id=1202794239621/Over-2000-Accutane-Suits-Revived-Appeals-Court-Says-Trial-Judge-Exceeded-Gatekeeper-Role, which reinstated 2,100 plaintiffs' suits based on its finding that the judge below went beyond his role as gatekeeper. The Accutane case has drawn amicus curiae briefs from several dozen parties who say the case provides an opportunity for the court to clarify New Jersey's expert witness stand. Some asked the court to adopt the standard from Daubert https://supreme.justia.com/cases/federal/us/509/579/case.html v. Merrell Dow Pharmaceuticals, a 1993 U.S. Supreme Court ruling governing admission of expert testimony. The Daubert standard refers to a series of guidelines for courts to use when evaluating scientific expert testimony. New Jersey, along with New York and Pennsylvania, are among nine states that have not adopted the Daubert standard. "The position we are taking on behalf of those amici is that the time has come for New Jersey to join the majority of other states and the federal court system and adopt the Daubert standard for admission of expert testimony. It's been our position that the rules for expert admission as applied in New Jersey state court are weaker than they are in the federal court system and the other states. That creates a problem where a case that couldn't survive in the federal courts and in the other jurisdictions are filed here in New Jersey in hopes of getting a jury trial on expert testimony that just isn't reliable," said Edward Fanning of McCarter & English in Newark, who submitted an amicus brief for the New Jersey Chamber of Commerce and three other business groups. The expert testimony issue arose in multicounty litigation by Accutane users before Superior Court Judge Nelson Johnson in Atlantic County. Johnson is hearing roughly 2,500 cases in which plaintiffs claim they developed Crohn's disease and other intestinal problems after taking Accutane. In February 2015, Johnson granted a defense motion to bar two medical experts—David Madigan, a statistician, and Arthur Kornbluth, a gastroenterologist—who gave the opinion that the epidemiology studies on which the defense relied were flawed and unreliable, and that Accutane can cause Crohn's disease. A few months later, in May 2015, Johnson dismissed 2,076 cases in light of the evidentiary ruling. But this July the Appellate Division reversed Johnson's ruling and reinstated the cases, finding he exceeded his role as gatekeeper when he concluded that plaintiffs' experts lacked credibility. The panel said Johnson wrongly condemned the experts for relying on scientific evidence other than epidemiological studies, despite their plausible explanations for doing so. Hoffmann-La Roche asked the Supreme Court to hear the case on Aug. 28. In filings with the court, the company said that the Appellate Division ruling, if allowed to stand, would "replace gate-keeping with a rule that allows any credentialed expert to argue their way to a jury, regardless of whether the argument is coherent or scientifically founded." Plaintiffs asked the court to deny certification on Sept. 12. In a filing with the court they said the drugmaker has wrongly accused the Appellate Division of eviscerating meaningful gatekeeping. They claim that the drugmaker's criticism of the methodology of plaintiffs' experts is premised on the erroneous belief that epidemiology studies do not show a connection between Crohn's and Accutane and that all other types of evidence should be disregarded. Rather, the analysis and testimony of the experts at issue "demonstrates that Roche's stark and blind reliance on purported study findings without consideration of limitations

and biases was contrary to good science and itself unreliable," the plaintiffs said in their petition to the Supreme Court. Rebecca Phillips, a Hoffmann-La Roche spokeswoman, said in a statement about the Supreme Court appeal, "Given the striking consensus in the medical, academic, and business communities about the importance of this issue and the error of the Appellate Division's ruling, we hope the Supreme Court will hear Roche's request to clarify the standards for expert admissibility in New Jersey." **AARS Update:** The Supreme Court has received an amicus curiae brief from the American Medical Association and the Medical Society of New Jersey, American Acne and Rosacea Society, American Academy of Dermatology, Society for Investigative Dermatology, and Dermatological Society of New Jersey; and one from four business groups—the HealthCare Institute of New Jersey, the New Jersey Business and Industry Association, the Commerce and Industry Association of New Jersey, and the New Jersey Chamber of Commerce. Also submitting amicus briefs are 21 corporations doing business in the state, including Benjamin Moore & Co., Verizon Communications, Celgene Corp., Eisai Inc., Merck Sharp & Dohme, Bristol-Myers Squibb and Bayer U.S.; and eight law professors. All asked the court to clarify New Jersey's standard for evaluating expert witnesses, and some groups asked the court to adopt Daubert. The New Jersey Supreme Court has agreed to hear the case. AARS President Julie Harper commented, "We are pleased to have been part of the Accutane appeal. Given the importance of this case from a medical, scientific, and ethical perspective, the AARS and the other leading societies and organizations involved, understood the impact this decision would have on the ability of dermatologists and other physicians to carry out their legal and ethical obligation to provide their patients with information necessary to provide informed consent to taking isotretinoin or in the future, other drugs."

Accuitis, Inc., announces clinical studies are underway for its rosacea therapeutic candidate, ACU-D_1. January 4, 2018 Press Release. http://accuitis.com/

Press Release: Alpharetta, GA. (Business Wire) Accuitis, Inc. today announced their phase 2 study (ACU-D1-201 study) is currently underway with over 25 patients enrolled to date. The study is evaluating the efficacy and safety of a ACU-D1 in patients with Rosacea (sub-type 2). ACU-D1, is a novel topical proteasome inhibitor discovered at Emory University. Rosacea, a dermatological condition which effects over 43 million people in the US & Western Europe. Rosacea sub-type 2 is typically classified is characterized by the appearance of inflammatory lesions (papules and pustules). "We are excited about the potential our first in class compound ACU-D1 may offer patients whom suffer with Rosacea (sub-type 2), many whom are frustrated with current therapeutic options for this condition." stated Rick Coulon, President & CEO of Accuitis, Inc. About Accuitis, Inc.: Accuitis, Inc., headquartered in Alpharetta, GA, is a clinical-stage biopharmaceutical company developing multiple first-in-class drug therapies to treat chronic, diseases of the skin and eye. Visit www.accuitis.com for more information. Contacts: Accuitis, Inc. Rick Coulon, Chief Executive Officer info@accuitis.com

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Foamix announces positive results from phase 3 open-label safety extension evaluating FMX-101 topical minocycline foam for treatment up to 1 year. Foamix Press Release. January 4, 2018. http://investors.foamix.com/2018-01-04-Foamix-Announces-Positive-Results-from-Phase-3-Open-Label-Safety-Extension-Evaluating-FMX-101-Topical-Minocycline-Foam-for-Treatment-up-to-1-Year

Rehovot, Israel, and Bridgewater, NJ – January 4, 2018 – Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX), ("Foamix"), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical foams to address unmet needs in dermatology, today announced positive safety data for its Phase 3 open-

label safety extension study, evaluating FMX-101 in moderate-to-severe acne for a treatment period of up to 1 year. The open-label safety extension enrolled a total of 657 patients, all of whom had completed 12 weeks of FMX-101 or vehicle treatment in the preceding double-blind phases of FX2014-04 or FX2014-05. Patients continued for up to an additional 40 weeks of open-label treatment with FMX-101. 291 patients completed a total of 52 weeks on FMX-101 therapy which is in excess of the subject sample size requirements specified in the regulatory guidance for this type of safety evaluation (ICH E1A, 1995). The key findings from the study are as follows: Non-dermal adverse events were comparable in type and frequency with those reported during the double-blinded portion of FX2014-04 and FX2014-05. The most frequently reported treatment-emergent adverse event was nasopharyngitis (common cold). In the open-label extension, 3 patients discontinued the study for non-dermal adverse events – abdominal pain (2 patients), back pain (1 subject). No serious drug-related adverse events were reported. Application site adverse events occurred in less than 2% of patients during the additional 40 weeks of open-label treatment with FMX-101. Four patients discontinued in the study for an application site adverse event – worsening of acne (2 patients), contact dermatitis (one subject), and localized facial edema (1 subject). In the assessment of facial dermal tolerability at Week 52, more than 95% of patients had “none” or “mild” signs and symptoms (erythema, dryness, hyperpigmentation, peeling, and itching), and no severe local tolerability scores were recorded. Subject satisfaction with FMX-101 treatment remained high when re-assessed at Week 52 which was consistent with scores obtained at Week 12 (end of double-blind phase). “We are extremely encouraged that our comprehensive safety evaluation of FMX-101 has validated earlier data demonstrating that FMX-101 appears to be well tolerated, with an acceptable safety profile and very positive patient survey results in the treatment of moderate-to-severe acne vulgaris,” said David Domzalski, CEO of Foamix.

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New Medical Research

Innate immunity in rosacea. Langerhans cells, plasmacytoid dentritic cells, toll-like receptors and inducible oxide nitric synthase (iNOS) expression in skin specimens: case-control study. Moura AKA, Guedes F, Rivitti-Machado MC, Sotto MN. Arch Dermatol Res. 2018 Jan 12. doi: 10.1007/s00403-018-1806-z. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29330632

Rosacea is a chronic inflammatory condition with predominant facial involvement. Because of that, many patients sense that rosacea affects quality of life. The etiology of rosacea remains unknown. Recent studies have suggested that aberrant innate immunity is central to this disease. The aim of this study was to examine the presence of Langerhans cells, plasmacytoid dentritic cells (PDC), the expression of Toll-like receptors (TLR) and inducible oxide nitric synthase (iNOS) in skin of patients with rosacea, to highlight the participation of innate immunity in its pathogenesis. 28 biopsy specimens were taken from patients with clinical and histopathological findings of rosacea. Immunohistochemical demonstration of Langerhans cells (anti-CD1a antibody), PDC (anti-CD 123 antibody), TLR2, TLR4 and iNOS was performed in skin samples and compared with normal skin controls. The expression of Langerhans cells was lower in rosacea group than in control group. PDC were found in skin samples of rosacea as isolated cells and forming small clusters. Expression of TLR2, TLR4 and iNOS was higher in rosacea samples than in normal skin controls. This research demonstrates early and late stage components of innate immunity in specimens of rosacea ratifying the existence of an altered innate immunity in its pathogenesis.

Pivotal trial of the efficacy and safety of oxymetazoline cream 1.0% for the treatment of persistent facial erythema associated with rosacea: findings from the first REVEAL trial. Kircik LH, DuBois J, Draelos ZD, et al. J Drugs Dermatol. 2018 Jan 1;17(1):97-105. https://www.ncbi.nlm.nih.gov/pubmed/29320594

An unmet need exists for a safe, tolerable, effective treatment for moderate to severe persistent facial erythema in patients with rosacea. This pivotal phase 3, multicenter, double-blind study evaluated the efficacy and safety of topical oxymetazoline in patients with facial erythema associated with moderate to severe rosacea. Patients were randomly assigned to treatment with oxymetazoline hydrochloride cream 1.0% or vehicle applied once daily for 29 days, and were followed for 28 days posttreatment. The primary efficacy outcome was having at least a 2-grade decrease from baseline on both the Clinician Erythema Assessment (CEA) and the Subject Self-Assessment for rosacea facial redness (SSA) scales (composite success) at 3, 6, 9, and 12 hours postdose on day 29. Safety assessments included treatment-emergent adverse events (TEAEs) and posttreatment worsening of erythema (composite CEA/SSA increase of 1-grade severity from baseline; rebound effect). A total of 440 patients (mean age, 49.5 years; 78.9% females) were randomized (oxymetazoline, n=222; vehicle, n=218); most had moderate erythema. On day 29, significantly greater proportions of oxymetazoline recipients achieved the primary efficacy outcome at each time point (P less than 0.02) and overall (P less than 0.001) compared with vehicle recipients. The incidence of discontinuation due to TEAEs was low in both groups (oxymetazoline group, 1.8%; vehicle group, 0.5%). The most common TEAEs reported during the entire study period were application-site dermatitis, application-site erythema, and headache in the oxymetazoline group (1.4% each), and headache (0.9%) in the vehicle group. Following cessation of treatment, low proportions of patients experienced rebound effect (oxymetazoline group, 2.2%; vehicle group, 1.1%). Oxymetazoline applied to the face once daily for 29 days was effective, safe, and well tolerated in patients with moderate to severe persistent facial erythema of rosacea.

Demodex and rosacea: Is there a relationship? Gonzalez-Hinojosa D, Jaime-Villalonga A, Aguilar-Montes G, Lammoglia-Ordiales L. Indian J Ophthalmol. 2018 Jan;66(1):36-38. doi: 10.4103/ijo.IJO_514_17. https://www.ncbi.nlm.nih.gov/pubmed/29283119

PURPOSE: The objective of the study is to compare the frequency of Demodex on the eyelash follicle of patients with rosacea and referents without rosacea or ophthalmological disorders. METHODS: This is a comparative, open, observational, and cross-sectional study that included 41 patients diagnosed with rosacea and 41 referents without rosacea diagnosis or ophthalmic alterations. The individuals underwent a slit-lamp examination in which two eyelashes per eyelid were removed with fine forceps. The presence of Demodex was sought by direct visualization under a light microscope. The results were expressed as "positive" when at least one mite on one lash was found and "negative" when no mite was identified. Chi-square test was used to compare the presence of mites in both groups. RESULTS: Eighty-two study individuals (45 females and 37 males) were included, of which 41 patients were diagnosed with rosacea and 41 were without rosacea or ophthalmic alterations. The average mean age was 37 years with a minimum of 19 and a maximum of 87 years. Of the 41 patients with rosacea, 31 had erythematotelangiectatic rosacea and 10 had papulopustular rosacea. There were no patients with phymatous or ocular rosacea. The presence of Demodex was found in 32 patients: 24 patients with rosacea diagnosis (16 of the erythematotelangiectatic subtype and 8 of papulopustular subtype) and 8 patients without rosacea or ophthalmic alterations ($P \leq 0.001$). CONCLUSION: Rosacea was found to be a statistically significant risk factor for Demodex infestation in eyelashes, irrespective of age and sex, with a higher prevalence in papulopustular variety.

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Successful combined antibiotic therapy with oral clindamycin and oral rifampicin for pyoderma gangrenosum in patient with PASH syndrome. Lamiaux M, Dabouz F, Wantz M, et al. JAAD Case Rep. 2017 Dec 18;4(1):17-21. doi: 10.1016/j.jdcr.2017.05.005. eCollection 2018 Jan. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5739174/

Pyoderma gangrenosum (PG) is a neutrophilic dermatitis, the prevalence of which is unknown. The only reported incidence in the literature estimates that there are 3 to 10 cases per million annually in the United Kingdom. The association with digestive tract and inflammatory rheumatic disease, neoplasia, and endocrinopathies is well known. New autoinflammatory syndromes with PG have been described: PAPA syndrome, combining PG with pyogenic sterile arthritis and cystic acne; PASH syndrome, combining PG with cystic acne and hidradenitis suppurativa (HS); and PAPASH syndrome, combining PG with pyogenic sterile arthritis, acne, and HS. PAPA and PAPASH syndromes arise from mutations in the coding region of the proline-serine-threonine-phosphatase interacting protein gene (PSTPIP1) resulting in the loss of inhibitory effect on the NALP3 inflammasome with production of interleukin (IL)-1β. For PASH syndrome, the only known anomaly is an increase in the number of CCTG repetitions in the PSTPIP1 promoter, with no known functional impact. First-line treatment for PG is generally based on systemic corticosteroid therapy or antibiotics with an anti-inflammatory action (eg, dapsone and tetracyclines) or immunosuppressive drugs (eg, azathioprine, cyclosporine, and mycophenolate mofetil). Also introduced recently are anti–tumor necrosis factor-α agents, anti–IL-1 (anakinra), and finally anti–IL-12–IL-23 (ustekinumab) and anti–IL-17 (ixekizumab). Studies investigating PASH syndrome found that cyclosporine and dapsone and biotherapy using anti–tumor necrosis factor-α5 and anti–IL-1 (anakinra)4 are effective. The clinical course is, however, marked by the risk of repeated relapses and resistance to conventional treatments for PG. Furthermore, any proposed therapeutic strategy should be effective against all 3 entities (ie, PG, HS, and cystic acne).

G2A attenuates propionibacterium acnes induction of inflammatory cytokines in human monocytes. Park AJ, Agak GW, Qin M, et al. Ann Dermatol. 2017 Dec;29(6):688-698. doi: 10.5021/ad.2017.29.6.688. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5705349/

BACKGROUND: Acne vulgaris is a disease of the pilosebaceous unit characterized by increased sebum production, hyperkeratinization, and immune responses to Propionibacterium acnes (PA). Here, we explore a possible mechanism by which a lipid receptor, G2A, regulates immune responses to a commensal bacterium. OBJECTIVE: To elucidate the inflammatory properties of G2A in monocytes in response to PA stimulation. Furthermore, our study sought to investigate pathways by which lipids modulate immune responses in response to PA. METHODS: Our studies focused on monocytes collected from human peripheral blood mononuclear cells, the monocytic cell line THP-1, and a lab strain of PA. Our studies involved the use of enzyme-linked immunosorbent, Western blot, reverse transcription polymerase chain reaction, small interfering RNA (siRNA), and microarray analysis of human acne lesions in the measurements of inflammatory markers. RESULTS: G2A gene expression is higher in acne lesions compared to normal skin and is inducible by the acne therapeutic, 13-cis-retinoic acid. In vitro, PA induces both the Toll-like receptor 2-dependent expression of G2A as well as the production of the G2A ligand, 9-hydroxyoctadecadienoic acid, from human monocytes. G2A gene knockdown through siRNA enhances PA stimulation of interleukin (IL)-6, IL-8, and IL-1β possibly through increased activation of the ERK1/2 MAP kinase and nuclear factor kappa B p65 pathways. CONCLUSION: G2A may play a role in quelling inflammatory cytokine response to PA, revealing G2A as a potential attenuator of inflammatory response in a disease associated with a commensal bacterium.

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Characterization of the facial microbiome in twins discordant for rosacea. Zaidi AK, Spaunhurst K, Sprockett D, et al. Exp Dermatol. 2017 Dec 28. doi: 10.1111/exd.13491. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29283459

Previously, we determined that genetic and environmental factors contributed equally towards rosacea in twins. To assess an environmental factor, we characterized the malar cheek bacterial microbiome from twins discordant for rosacea. We found no significant difference in facial microbiome alpha and beta diversity between related twins discordant for rosacea. However, the relative percentage abundance of Gordonia and Geobacillus, low abundant genera, was positively and negatively associated with rosacea severity, respectively. Our data demonstrate a significant correlation between facial microbiome and severity of rosacea in genetically matched twins and importantly that overall microbiome composition is largely unchanged.

Clinical Reviews

Prevalence of gastrointestinal comorbidities in rosacea: Comparison of subantimicrobial, modified release doxycycline versus conventional release doxycycline. Lim HG, Fischer A, Rueda MJ, et al. J Am Acad Dermatol. 2018 Feb;78(2):417-419. doi: 10.1016/j.jaad.2017.08.027. https://www.ncbi.nlm.nih.gov/pubmed/29332715

To the Editor: Rosacea has been associated with an increased prevalence of gastrointestinal diseases (GIDs), which correlates with skin severity. Oral doxycycline is frequently prescribed for moderate to severe rosacea. In subantimicrobial doses, doxycycline provides an antiinflammatory effect while avoiding the risks of long-term antibiotic use thought to occur with conventional doses (100 mg). Currently, a subantimicrobial dose (40 mg) is the only approved systemic therapy for the inflammatory lesions of rosacea; however, costs and insurance practices may be prohibitive, and conventional doses are often prescribed. With doxycycline's well-established gastrointestinal side effects, we hypothesize that the association between rosacea and GID may be mediated in part by doxycycline usage. We compared different doxycycline doses (subantimicrobial dose, modified release [SD] of 40 mg to conventional, regular release dosages [CD] of 50 or 100 mg) for GID prevalence.

Ablative fractional CO2 laser for facial atrophic acne scars. Xu Y, Deng Y. Facial Plast Surg. 2018 Jan 5. doi: 10.1055/s-0037-1606096. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29304516

Ablative fractional carbon dioxide laser resurfacing is a well-established treatment for acne scars. However, there are limited consensus and guidelines regarding the procedure, such as its treatment plan, efficacy, and safety. In this study, we performed a systematic review to assess the efficacy and safety of the fractional carbon dioxide laser treatment procedure, and to provide evidence-based recommendations concerning its practical use on atrophic acne scars. A comprehensive search was performed in, EMBASE, Ovid, Web of Science, and Cochrane databases, using the keywords "scar(s)," "acne vulgaris," "carbon dioxide," and "fraction* laser(s)" for the period from January 1987 to December 2016. The initial literature search identified 337 articles. The final selection included 30 studies: 12 retrospective studies and 18 prospective randomized clinical trials. Ablative fractional carbon dioxide laser is an effective therapy for the treatment of acne scars. The treatment session, interval, and parameters should be

customized for each patient. Combination therapy should be considered for ice-pick type acne scars. The use of dermocosmetics in pre- and postoperative care may be beneficial to patients.

Isotretinoin-induced acne fulminans without systemic symptoms with concurrent exuberant granulation tissue. Li AW, Antaya RJ. Pediatr Dermatol. 2018 Jan 4. doi: 10.1111/pde.13389. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29314240

Acne fulminans is a severe form of acne characterized by painful, inflammatory nodules that progress into ulcers and concurrent systemic symptoms. Treatment of acne with isotretinoin can precipitate a syndrome called isotretinoin-induced acne fulminans without systemic symptoms. An exuberant granulation tissue response, another known adverse event associated with isotretinoin, can occur concurrently, inhibiting wound repair and complicating treatment. We report a case of isotretinoin-induced acne fulminans without systemic symptoms with exuberant granulation tissue response that was treated successfully with topical clobetasol ointment.

Pityriasis folliculorum: response to topical ivermectin. Darji K, Burkemper NM. J Drugs Dermatol. 2017 Dec 1;16(12):1290-1292. https://www.ncbi.nlm.nih.gov/pubmed/29240866

Pityriasis folliculorum has been described as a dry type of rosacea with extensive proliferation of Demodex folliculorum in pilosebaceous follicles of the skin. This skin condition is frequently difficult to manage, with various treatment options showing mixed efficacy. Oral ivermectin, a macrocyclic lactone parasiticide with anti-inflammatory and anti-parasitic effects, is one of the leading treatment modalities for demodicosis. Topical ivermectin has recently been FDA approved as therapy for rosacea. We present the case of a woman with pityriasis folliculorum who showed significant improvement from using topical ivermectin with no adverse events related to treatment.

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The latest drugs and small molecule inhibitors for skin and hair. Kalhun V, Sadick N. J Drugs Dermatol. 2017 Dec 1;16(12):1224-1228. https://www.ncbi.nlm.nih.gov/pubmed/29240857

Biologic drugs, a novel class of agents engineered to target specific mediators of inflammation, and small-molecule inhibitors that penetrate the cell membrane to interact with targets inside a cell represent the cutting-edge of pharmacological biomedical therapeutics. Clinical studies have already demonstrated the effectiveness of this new generation of drugs in treating a variety of medical illnesses and conditions that were refractory to traditional treatments. This review aims to describe the latest available or currently in-development drugs, biologic agents, and small molecule inhibitors for treatment of psoriasis, rosacea, alopecia areata, and atopic dermatitis.

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Retinoic acid embryopathy. Mondal D, R Shenoy S, Mishra S. Int J Appl Basic Med Res. 2017 Oct-Dec;7(4):264-265. doi: 10.4103/ijabmr.IJABMR_469_16. https://www.ncbi.nlm.nih.gov/pubmed/29308367

Isotretinoin is a retinoid which is derived from Vitamin A. It is indicated for severe cystic acne treatment, but it has been classified as teratogenic. A wide spectrum of birth defects including craniofacial, heart, and nervous system malformations have been described with prenatal exposure to this drug. We report the case of a newborn with a

history of prenatal exposure to isotretinoin with craniofacial defects, including left-sided anotia, right-sided microtia, complex congenital heart disease, and central nervous system malformation.

Patient Counseling/Communication

Patients' self-esteem before and after chemical peeling procedure. Anargyros K, Eftychia P, Christos C, et al. J Cosmet Laser Ther. 2017 Dec 29:1-3. doi: 10.1080/14764172.2017.1400168. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/29286838

INTRODUCTION: Chemical peeling is a safe method, widely used to treat a variety of skin conditions and reduce the aging effects. This study aims to evaluate self-esteem among adolescents who undergo chemical peelings. MATERIAL AND METHODS: One hundred and twenty six patients constituted the study group. Sixty seven individuals had undergone chemical peeling for therapeutic reasons and 59 individuals for cosmetic reasons. To assess patients' self-esteem, the Rosenberg's Self-esteem Scale (RSES) was used before and after treatment. The control group included 71 healthy, age- and sex-matched volunteers from the general population. They were also asked to complete the RSES, after the same time interval as the patients. RESULTS: The healthy controls (23.01 ± 3.12) presented statistically significantly higher self-esteem than both the groups of individuals who would be submitted to chemical peeling. Furthermore, patients who would undergo peeling for therapeutic reasons (21.58 ± 3.20) had statistically significantly higher self-esteem than those who would undergo the procedure for cosmetic reasons (18.97 ± 3.36). After the chemical peeling sessions, the self-esteem of patients treated for therapeutic reasons (23.48 ± 2.43) and of patients treated for cosmetic reasons (22.83 ± 3.34) improved statistically significantly, while the self-esteem of the healthy controls remained stable, as expected. CONCLUSION: Patients who undergo chemical peelings tend to have low levels of self-esteem. Although facial lesions in skin diseases such as acne, acne scars, rosacea, and melasma seem to have negative effect on individuals' self-consciousness, patients who would be submitted to chemical peeling in order to treat wrinkles, loss of radiance, and skin tone clarity have even lower self-esteem. Chemical peelings were shown to favorably affect patient's self-esteem since all patients showed an increase in self-esteem after treatment, while the control group experienced no change.

Debunking acne myths: Do patients need to worry about acne after adolescence? January 10, 2018. MDedge, Cutis. https://www.mdedge.com/cutis/article/155950/acne/debunking-acne-myths-do-patients-need-worry-about-acne-after-adolescence?channel=171

Acne typically is associated with teenagers and puberty, and many adult patients may not be aware that acne can persist beyond adolescence or even develop for the first time in adulthood. As the prevalence of adults with acne increases, it is important to educate this population about factors associated with postadolescent acne development and let them know that effective treatments are available. There are 2 types of adult acne: persistent acne, which refers to adolescent acne that continues beyond 25 years of age, and late-onset acne, which develops for the first time after 25 years of age. Adult acne generally is mild to moderate in severity and may be refractory to treatment. Unlike adolescent acne, which is more prominent in adolescent boys and manifests as the more severe forms of the disease, adult acne primarily affects women and is more inflammatory in nature, making these patients more susceptible to scarring. In one study, acne prevalence among 1055 adult participants (age range, 20–60 years) was estimated at 61.5%; however, only 36.8% were aware of their condition and only 25% sought treatment. The most

commonly affected area was the malar region, which differs from acne seen in teenagers. In addition to the cheeks, adult acne generally is more prominent on the lower chin, jawline, and neck, and lesions more commonly present as closed comedones. Fluctuating hormone levels are a common cause of adult acne, particularly in women during menses or pregnancy, menopause, or perimenopause; women also may experience breakouts after starting or discontinuing birth control pills. Acne flare-ups in adults also have been linked to chronic stress, family history, hair and skin care products, medication side effects, undiagnosed medical conditions, steroid use, increased calorie intake, whole and fat-reduced milk consumption, and tobacco smoking. Adult acne also has been found to be associated with other dermatologic conditions including hirsutism, alopecia, and seborrhea. Early diagnosis and treatment of adult acne is crucial to ensure good cosmetic outcomes and minimize disease burden. When treating adult acne, particularly in women, dermatologists should consider a variety of factors that set this condition apart from adolescent acne, including the predisposition of older skin to irritation, possible slow response to treatment, a high likelihood of good adherence to treatment, and the psychosocial impact of acne in the adult population. In adult women, it also is important to consider whether patients are of childbearing age when selecting a treatment. Patients also should be encouraged to read the labels on their personal care products to ensure they are noncomedogenic and will not clog pores.