AARS HOT TOPICS MEMBER NEWSLETTER

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Industry News

Dermira completes patient enrollment in two phase 3 pivotal trials of olumacostat glasaretil for the treatment of acne vulgaris. Press Release By: Dermira October 5, 2017. http://investor.dermira.com/phoenix.zhtml?c=253686&p=irol-newsArticle&ID=2304857

MENLO PARK, Calif., Oct. 05, 2017 (GLOBE NEWSWIRE) -- Dermira, Inc. (NASDAQ:DERM), a biopharmaceutical company dedicated to bringing biotech ingenuity to medical dermatology by delivering differentiated, new therapies to the millions of patients living with chronic skin conditions, today announced the completion of patient enrollment in its CLAREOS-1 and CLAREOS-2 Phase 3 clinical trials. Both trials are designed to evaluate the efficacy and safety of olumacostat glasaretil (formerly DRM01) in patients ages nine years and older with facial acne vulgaris. Olumacostat glasaretil is a novel, small molecule designed to target sebum production following topical application. “Despite the number of options currently available to treat acne, the majority of these treatments have been available for more than 30 years, and patients of all ages continue to seek new options to effectively and safely manage this common skin condition,” said Luis Peña, chief development officer at Dermira. “We continue to believe that olumacostat glasaretil represents a potential new treatment option for acne with an exciting new mechanism of action that is designed to target sebum, and we look forward to sharing topline results from the Phase 3 clinical program in the first quarter of next year.” Dermira expects to announce topline efficacy and safety results from the CLAREOS-1 and CLAREOS-2 studies in the first quarter of 2018. CLARITUDE, a third trial assessing the long-term safety of olumacostat glasaretil, will continue for an additional nine months. Positive results from CLAREOS-1 and CLAREOS-2, the completion of CLARITUDE and other registration-enabling studies and activities are required to support a potential New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for olumacostat glasaretil. About Olumacostat Glasaretil Phase 3 Program: The Phase 3 clinical program consists of two randomized, multi-center, double-blind, parallel-group, vehicle-controlled trials, CLAREOS-1 and CLAREOS-2, designed to assess the efficacy and safety of olumacostat glasaretil compared to vehicle to support a potential NDA submission to the FDA. The program enrolled total of 1,503 patients (CLAREOS-1, n=759 and CLAREOS-2, n=744) ages nine years and older with moderate-to-severe acne vulgaris at 94 sites in the United States, Canada and Australia. In each trial, patients were randomized in a 2:1 fashion to receive either olumacostat glasaretil at a concentration of 5% or vehicle twice daily for 12 weeks. Consistent with the design of two earlier Phase 2 trials, inclusion criteria required a minimum of 20 inflammatory and 20 non-inflammatory facial lesions and an Investigator’s Global Assessment (IGA) score of three or four on a five-point scale that ranges from a score of zero, representing clear skin, to a score of four, representing severe disease. The primary endpoints of both trials will evaluate the absolute changes from baseline in inflammatory and non-inflammatory lesion counts and the proportion of patients achieving at least a two-grade improvement from baseline to a grade of 0 or 1 on the five-point IGA scale. Secondary endpoints will evaluate the percentage change from baseline in inflammatory and non-inflammatory lesion counts on the face and the proportion of patients achieving at least a two-grade improvement from baseline on the five-point IGA scale. All efficacy endpoints will be measured at the end of the 12-week treatment period. Safety will also be assessed. The Phase 3 program also includes an open-label study, CLARITUDE, assessing the long-term safety of olumacostat glasaretil, in which patients from either of the two Phase 3 studies will be permitted to continue to receive treatment for up to an additional 36 weeks. About Olumacostat Glasaretil: Olumacostat glasaretil is a novel, small molecule designed to target sebum production following topical application. Sebum is an oily substance made up of lipids produced by glands in the skin called sebaceous glands, and excessive sebum production is an important aspect of acne that is not addressed by available topical therapies. Olumacostat glasaretil is designed to exert its effect by inhibiting acetyl coenzyme-A

carboxylase, an enzyme that plays an important role in the synthesis of fatty acids, a type of lipid that represents an essential component of the majority of sebum lipids.

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New Medical Research

Intense pulsed light treatment for patients with hidradenitis suppurativa: beware treatment with resorcinol. Theut Riis P, Saunte DM, Sigsgaard V, et al. J Dermatolog Treat. 2017 Oct 3:1-9. doi: 10.1080/09546634.2017.1387226. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28972804

BACKGROUND: HS is a debilitating chronic skin disease of the hair follicle. Intense pulsed light therapy has been suggested for treatment of HS. In this letter we report a retrospective chart review of the Hidradenitis Suppurativa patients we have treated so far. MATERIAL AND METHOD: Twenty-five patients were treated with the Palomar LuxY IPL. Patients were treated with a pulse width of either 20 or 100 nm, using a fluence between 18 and 34 J/cm2

depending on the area treated, pain response and skin type. Patients were treated every 4 to 6 weeks. Results were gathered from medical charts Results: A total of 13 of 25 patients reported a reduction in disease activity and 17 of 25 reported an effect on hair growth. A reduction in disease activity co-occurred with a reduction in hair growth in all cases ($p = 0.001$). Seven patients experienced adverse effects, all of these patients were in concomitant Resorcinol treatment ($p = 0.020$). Patients with effect on disease activity had a mean of 7.46 treatments with patient without effect had a mean of 4.0 treatments. CONCLUSION: We suggest IPL as an adjuvant treatment, but advice caution when using IPL and topical Resorcinol in conjunction.

Fractional carbon dioxide laser for the treatment of facial atrophic acne scars: prospective clinical trial with short and long-term evaluation. Elcin G1, Yalici-Armagan B2. Lasers Med Sci. 2017 Sep 11. doi: 10.1007/s10103-017-2322-7. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28894992

The aim of this study was to evaluate the efficacy and safety of fractional carbon dioxide laser for the treatment of acne scars. Thirty-one participants, 15 female and 16 male, whose mean age was 34.84 ± 10.94 years, were included in this prospective study. The study took place between 2012 and 2016. Participants were evaluated with the "ECCA Grading Scale" before the first session, 3 months (short-term evaluation) and 3 years after the last session (long-term evaluation). Participants received two or three treatment sessions at 4-week intervals, with a 10,600 nm fractional carbon dioxide laser with pulse energies ranging between 100 and 160 mJ, 120 spot type, 75-100 spot/cm2 density, and 30 W power. Self-assessments by the participants were done 3 months and 3 years after the last session. The mean ECCA score was 107.90 ± 39.38 before the first session, and 82.17 ± 36.23 at the time of short-term evaluation ($p = 0.000$). The grade of improvement at the short-term evaluation was as follows: no improvement, mild, moderate, and significant improvement for 7 (22.6%), 11 (35.5%), 9 (29%), and 4 (12.9%) of the participants, respectively. Regarding self-assessments, 80.6 and 61.3% of the participants rated themselves as having at least mild improvement at the short-term and the long-term follow-up periods, respectively. The results of this study suggest that fractional carbon dioxide laser is an efficient treatment option for acne scars. Furthermore, self-assessment results show that more than half of the participants still experience at least mild improvement at the end of 3 years.

Treatment of acne scarring with a novel fractionated, dual-wavelength, picosecond-domain laser incorporating a novel holographic beam-splitter. Bernstein EF1, Schomacker KT2, Basilavecchio LD1, et al. Lasers Surg Med. 2017 Sep 28. doi: 10.1002/lsm.22734. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28960395

BACKGROUND AND OBJECTIVES: Fractional treatment with a dual wavelength 1,064 and 532 nm picosecond-domain laser, delivering a 10 × 10 array of highly focused beamlets via a holographic optic, was investigated for the treatment of acne scars. STUDY: Twenty-seven of 31 subjects completed the study, 19 were treated using 1,064 nm and 8 were treated at 532 nm, all having four-monthly treatments. Blinded evaluation of digital images by three physician evaluators comparing pre- and 3-month post-treatment images measured efficacy using a 10-point scale. Subject self-assessment of treatment effects were also recorded. Safety was measured by recording subject discomfort scores and adverse effects. RESULTS: Blinded reviewers correctly identified the baseline image in 61 of the 81 image sets (75%), and baseline acne scar scores were 1.8 ± 0.7 and 1.8 ± 0.5 for the 1,064 and 532 nm cohorts, and decreased to 1.1 ± 0.5 ($P < 0.001$) and 1.1 ± 0.0 ($P < 0.005$), respectively. Post-treatment erythema, mild edema, and petechiae were the only side effects noted. CONCLUSION: The 1,064 and 532 nm picosecond-domain laser incorporating a 10 × 10 holographic beam-splitting handpiece was found to be safe and effective for the treatment of facial acne scars. The treatments were well tolerated and the subjects experienced little to no downtime.

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Clinical Reviews

Pulsed dye laser treatment combined with oral minocycline reduces recurrence rate of rosacea. Ko HS, Suh YJ, Byun JW, Choi GS, Shin J. Ann Dermatol. 2017 Oct; 29(5):543-547. doi: 10.5021/ad.2017.29.5.543. Epub 2017 Aug 25. https://www.ncbi.nlm.nih.gov/pubmed/28966509

BACKGROUND: The recurrence rate of rosacea was not known very well, but has been reported as 60% in 6 months after withdrawal of the drug. It is not known which treatment can reduce relapses of rosacea effectively. OBJECTIVE: The objective was to identify whether 595 nm-pulsed dye laser (PDL) treatment reduced recurrence rate among rosacea patients who were treated with oral minocycline. METHODS: One hundred and seven Korean patients with rosacea who started treatment with oral minocycline (100 mg/d) with or without PDL (2~4 sessions) were evaluated retrospectively. The recurrence rate was estimated using the Kaplan-Meier method, and difference was evaluated using the log-rank test. Cox proportional hazards model was used to estimate hazard ratios and 95% confidence intervals (CIs) of risk factors for the recurrence of rosacea. RESULTS: The recurrence-free survival analysis revealed that the group with oral minocycline plus PDL was significantly different compared with the group with oral minocycline alone (p=0.011). Cox proportional hazards model showed that the combined use of PDL with oral minocycline appeared to be a significant protective factor for the hazard of recurrence of rosacea (hazard ratio, 0.492; 95% CI, 0.257~0.941; p=0.032). CONCLUSION: PDL can be used added to oral minocycline to reduce relapses among rosacea patients who are undergoing oral minocycline treatment.

Comparative effects of schisandrin A, B, and C on Propionibacterium acnes-induced, NLRP3 inflammasome activation-mediated IL-1β secretion and pyroptosis. Guo M, An F, Yu H, et al. Biomed Pharmacother. 2017 Sep 30; 96:129-136. doi: 10.1016/j.biopha.2017.09.097. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28972885

Propionibacterium acnes, a common pathogen associated with acne, is also responsible for various surgical infections. Schisandrin A, schisandrin B and schisandrin C, the representative lignans of Schisandra chinensis (Turcz.) Baill. extract, inhibit P. acnes-induced inflammation. However, their effects on P. acnes-induced IL-1β secretion and pyroptosis mediated by NLRP3 inflammasome activation remain unknown. In this study, we compared the effects of schisandrin A, B, and C (Sch A, B, and C) on IL-1β secretion and pyroptosis in P. acnes-infected THP-1 cells. As NLRP3 plays important roles in P. acnes-mediated inflammation and pyroptosis, we also investigated the effects of Schs on P. acnes-induced NLRP3 inflammasome activation by measuring the levels of NLRP3, active caspase-1, and mature IL-1β, and activity of caspase-1. Our results showed that Sch A, B, and C suppressed P. acnes-induced pyroptosis. Further, the three lignans significantly suppressed NLRP3 inflammasome activation, with the following potency: Sch C > Sch B > Sch A. Three lignans also inhibited the production of mitochondrial ROS and ATP release. Additionally, Sch B and C almost completely prevented the efflux of K+., whereas Sch A had a relatively weak effect. Collectively, our novel findings showed that Sch A, B, and C effectively suppressed IL-1β secretion and pyroptosis by inhibiting NLRP3 inflammasome activation in P. acnes-infected THP-1 cells. Thus, Schs may be promising agents for the treatment of P. acnes-related infections.

The person-centered acne severity scale study. Patel DP, Bernardis E, Yan AC. Pediatr Dermatol. 2017 Sep 28. doi: 10.1111/pde.13262. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28960435

Acne is one of the most common skin conditions seen by dermatologists. As with many other cutaneous diseases, due to its visibility, acne often produces a large psychosocial impact on patients who suffer from the disease. Such psychosocial burdens are exacerbated by the variation in acne presentation that can lead to the usage of multiple different treatments before visible improvements are appreciated. Although many scales have been established to determine severity from the clinician standpoint, patient-oriented scales are lacking. Clinicians use these severity tools to guide management and judge patient improvement from visit to visit. Creation of such a severity scale from a patient's perspective would allow patients to not only assess their perception of their acne independent of a physician but could also be used to determine patient satisfaction with treatment that would then help to more effectively guide management. Therefore the goal of this study is to create and validate a patient-centered acne severity scale using a visual analogue scale format.

Hidradenitis suppurativa is associated with myocardial infarction, but not stroke or peripheral arterial disease of lower extremities. Miller IM, Ahlehoff O, Zarchi K, Rytgaard H, et al. Br J Dermatol. 2017 Sep 15. doi: 10.1111/bjd.15998. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28914960

We performed a comparative cross-sectional study of the potential association of HS and the three outcome events: self-reported MI, self-reported stroke, and PAD measured by ankle-brachial index (ABI) ≤ 0.9. We included a self-reported HS group (n=430) identified in the general suburban population study (GESUS) using a validated questionnaire 2 (Table 1).The control group comprised participants from GESUS without HS, n=20,780.

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Uncovering burden disparity: A comparative analysis of the impact of moderate-to-severe psoriasis and hidradenitis suppurativa. Hamzavi IH, Sundaram M, Nicholson C, Zivkovic M, et al. J Am Acad Dermatol. 2017 Sep 13. pii: S0190-9622(17)32156-4. doi: 10.1016/j.jaad.2017.07.027. [Epub ahead of print] https://www.ncbi.nlm.nih.gov/pubmed/28917381

BACKGROUND: Psoriasis and hidradenitis suppurativa (HS) exhibit distinct clinical features, but no studies have directly compared the health-related quality of life (HRQoL) in patients with moderate-to-severe manifestations of these conditions. OBJECTIVE: To determine which disease is associated with more severe HRQoL impairment. METHODS: Weighted averages of each of the following baseline HRQoL measures were determined and compared between HS and psoriasis populations from 5 clinical trials: Visual Analog Scale (VAS) for pain, Total Work Productivity Impairment, Dermatology Life Quality Index; EuroQOL 5D VAS, and Short Form-36 Health Survey. RESULTS: Compared with patients with psoriasis, patients with HS reported higher scores for VAS-pain (54.3 vs 36.1 [P < .0001]), Dermatology Life Quality Index (15.3 vs 11.3 [P < .0001]), EuroQOL 5D VAS (58.8 vs 50.8 [P < .0002]), and Total Work Productivity Impairment (35.4 vs 18.2). Patients with HS had lower Short Form-36 Health Survey scores than did patients with psoriasis (physical, 39.6 vs 49.0; mental, 41.5 vs 47.5 [both P < .0001]). LIMITATIONS: This analysis was performed using published summary data rather than patient-level data, and weighted pooled averages were compared. CONCLUSIONS: Patients with HS have a higher HRQoL burden than patients with psoriasis. This study clearly documents the needs of patients with HS and the potential impact of medical, scientific, and societal consensus for the development of more effective HS treatments.

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Role of demodex mite infestation in rosacea: A systematic review and meta-analysis. Chang YS1, Huang YC2. J Am Acad Dermatol. 2017 Sep;77(3):441-447.e6. doi: 10.1016/j.jaad.2017.03.040. https://www.ncbi.nlm.nih.gov/pubmed/28711190

BACKGROUND: The reported prevalence and degrees of Demodex mite infestation in rosacea vary widely. OBJECTIVE: We sought to conduct an evidence-based meta-analysis of the prevalence and degrees of Demodex mite infestation in patients with rosacea. METHODS: Systematic literature review and meta-analysis were conducted. Odds ratios for prevalence of infestation and standardized mean difference (SMD) for Demodex density in patients with rosacea were pooled. Subgroup analysis for type of rosacea, control group, and sampling and examination methods were also performed. RESULTS: Twenty-three case-control studies included 1513 patients with rosacea. Compared with the control patients, patients with rosacea were more likely to be infested by Demodex mites [odds ratio, 9.039; 95% confidence interval (CI), 4.827-16.925] and had significantly higher Demodex density (SMD, 1.617; 95% CI, 1.090-2.145). Both erythematotelangiectatic rosacea (SMD, 2.686; 95% CI, 1.256-4.116) and papulopustular rosacea (SMD, 2.804; 95% CI, 1.464-4.145) had significantly higher Demodex density than did healthy control patients. LIMITATIONS: Interstudy variability was high, and a causal relationship could not be established by case-control studies. CONCLUSIONS: Patients with rosacea had significantly higher prevalence and degrees of Demodex mite infestation than did control patients. Demodex mites may play a role in both erythematotelangiectatic rosacea and papulopustular rosacea.

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The burden of illness of erythematotelangiectatic rosacea and papulopustular rosacea: findings from a web-based survey. Del Rosso JQ1, Tanghetti EA2, Baldwin HE3, Rodriguez DA4, Ferrusi IL5. J Clin Aesthet Dermatol. 2017 Jun;10(6):17-31. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5605205/

Objective: Evaluate patients' perceptions of rosacea symptoms and treatments. Design: Cross-sectional, web-based survey conducted from May 8 to July 1,2015. Setting: E-mail invitation. Participants: Male and female adults in the United States who self-reported having a physician's diagnosis of rosacea. Measurements: Sociodemographic and clinical characteristics were collected for eligible respondents using the Self-Assessment of Rosacea Facial Redness scale and the Symptom Assessment for Rosacea Facial Bumps and Pimples questionnaire. Respondents were instructed how to differentiate erythematotelangiectatic rosacea and papulopustular rosacea. Use of different treatments and satisfaction with treatment were assessed, as were coping mechanisms. Results: More than 4,000 individuals responded and 600 completed the survey. The participants' mean age was 51.7 years and more than 90 percent rated their rosacea severity as mild or moderate. Most practiced stress and/or anxiety management, used makeup to cover rosacea, used sun protection, and changed their exercise regimens to cope with rosacea flare-ups. Participants reported avoiding sun exposure, hot baths and saunas, and specific skin care products to circumvent potential rosacea flare-ups. More than half (55.7%) had used a prescribed topical agent for rosacea in the preceding month, and 26.3 percent had used a prescribed oral antibiotic. Fewer than half were satisfied with treatment outcomes. Conclusion: Despite the chronic nature of rosacea, participants commonly used prescription agents only to treat flare-ups and relied on sun protection and other avoidance mechanisms to reduce their frequency. Education is needed to communicate the long-term nature of rosacea and the need for continued treatment to maintain long-term control.

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Treatment of moderate-to-severe acne vulgaris in a Hispanic population: A post-hoc analysis of the efficacy and tolerability of clindamycin 1.2%/ benzoyl peroxide 3.75% gel. Alexis AF1, Cook-Bolden F2, Lin T3. J Clin Aesthet Dermatol. 2017 Jun;10(6):36-43. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5605206/

Background: Acne vulgaris (acne) is highly prevalent in the Hispanic population as it is in other racial/ethnic groups. While nuances in the presentation, quality-of-life impact, and approach to therapy of acne have been reported in various racial ethnic groups and skin types, data on the Hispanic population are limited, and yet they are the fastest growing population in the United States. Potential for irritation, dryness, and pigmentary alteration (due to acne and/or treatment) are key concerns in the management of acne in Hispanic populations. Evaluation of the efficacy and tolerability of topical therapies in this growing segment of the population is therefore important. Methods: A post-hoc analysis of efficacy and cutaneous tolerability in 136 Hispanic subjects receiving clindamycin phosphate 1.2%/benzoyl peroxide (BP) 3.75% gel or vehicle from a 12-week, multicenter, double-blind study of 498 subjects with moderate-to-severe acne. Data was compared to that seen in the non-Hispanic population in the Phase 3 study. Results: Mean reductions in inflammatory and noninflammatory lesions (63.6% and 54.3%, respectively) were significantly greater with clindamycin phosphate 1.2%/BP 3.75% gel versus vehicle (P=0.001 and 0.008, respectively) and numerically greater than the reductions seen in the non-Hispanic population. Treatment success, a 2-grade reduction in severity from baseline (36.5%), was also greater than vehicle at Week 12. Cutaneous tolerability was excellent with all mean scores less than or equal to 0.2 at Week 12 (where 1=mild). No subjects discontinued due to adverse events. Conclusion: Clindamycin phosphate 1.2%/BP 3.75% gel was well tolerated and efficacious in the Hispanic population. Compared with the general population, Hispanic acne subjects were not

found to be more susceptible to cutaneous irritation from treatment with clindamycin phosphate 1.2%/BP 3.75% gel.

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Nonablative fractional laser resurfacing in skin of color: evidence-based review. Kaushik SB1, Alexis AF1. J Clin Aesthet Dermatol. 2017 Jun;10(6):51-67. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5605208/

Background: Nonablative laser resurfacing represents one of the major advances in procedural dermatology over the past decade. However, its use in darker skin types is limited by safety concerns and a relative lack of available data. Aim: To provide evidence-based recommendations for the use of fractional lasers in darker skin types. Evidence review: A broad literature search of PubMed/Medline database was conducted in April 2016 using the term fractional lasers. A free text search of keywords including fractional resurfacing, nonablative lasers, skin type, skin of color, ethnic skin, Fitzpatrick skin type, Asian skin, African Americans, Afro-Caribbean, and Hispanics was also executed. An in-depth review of all the relevant articles fitting the authors' inclusion/exclusion criteria was performed. Thereafter, each study was assigned levels of evidence per the Modified Criteria by Oxford Center of Evidence Based Medicine. A recommendation was made for a specific treatment based on the presence of at least one Level 1 study or more than three Level 2 or 3 studies that had concordant results. Findings: The available evidence strongly suggests that fractional lasers are a favorable treatment option for a variety of dermatological diseases in Fitzpatrick skin phototypes IV to VI. Level 1 evidence was found for the use of fractional lasers for treating acne, striae and skin rejuvenation. Level 2 evidence was found for their use in acne scars, melasma, and surgical/traumatic scars. Conclusion: Fractional resurfacing is a safe and efficacious treatment option for various dermatological disorders in darker skin types; however, there is a paucity of high-quality studies involving skin types V and VI.

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Patient Counseling/Communication

Living with acne: belief and perception in a sample of Indian youths. Kaushik M1, Gupta S1, Mahendra A1. Indian J Dermatol. 2017 Sep-Oct;62(5):491-497. doi: 10.4103/ijd.IJD_100_16. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5618836/

BACKGROUND: Acne vulgaris is a common disease among adolescent. There is paucity of information on knowledge and understanding of acne patients about their condition. OBJECTIVE: This study was carried out to evaluate beliefs and perception of acne patient toward their understanding of disease, treatment option, and information source. MATERIALS AND METHODS: A cross-sectional study was conducted on acne patients by means of a questionnaire during 2013-2014 at MMIMSR, Ambala. An adapted version of questionnaire of Brigitte et al. was used and was modified to suit Indian sentiments. RESULTS: A total of 200 acne patients were participated in the study. Mean age of participants was 19.80 years. Male:female ratio was 2:1. Causes implicated were diet (85%), puberty (65%), and mood swings (46%). Fatty food and stress were most common agents held responsible for acne flaring. Popular sources of information were friends and parents. 102 patients had used steroids one way or the other. Acne was considered curable by 65% with an anticipated duration of treatment lasting up to 12 months. CONCLUSION: Misconceptions are widespread among the population. A health education program is needed which should be included in school curriculum to improve their understanding of the condition.

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