Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

278

Photo validation study using cutaneous dermatomyositis disease area and severity index in dermatomyositis patients

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The Coronavirus disease 2019 (COVID-19) pandemic revealed our need for reliable tools to evaluate patients with skin disease virtually. Thus far, there has not been a study that has attempted to score the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI), a validated outcome measure of skin activity and damage, from photographs. In this study, patients were prospectively recruited during routine clinic visits and skin regions used in scoring the CDASI were photographed by research staff using two iPhone cameras (an iPhone 8 and iPhone 11). Two dermatologists served as the raters. The in-person CDASI assessment was scored by rater 1 at the clinic visit and the photographs were scored at a later date by both rater 1 and rater 2. Of the 34 patients participating in the study, 82.3% were female, 85.3% were Caucasian with a mean age of 54 years (SD=12). For the total activity score, the intraclass correlation coefficient (ICC) between rater 1's in-person assessment compared to photograph assessment was 0.806 (95% CI 0.649-0.898 p<0.001) and was 0.822 (95% CI 0.675-0.907 p<0.001) between rater 2 and the in-person assessment. For the total damage score, the ICC between rater 1 and the in-person assessment was 0.54 (95% CI 0.254-0.739 p=0.004) and was 0.601 (95% CI 0.338-0.778 p<0.001) between rater 2 and the in-person assessment. The reliability was interpreted as "excellent" for skin activity, an important measure in clinical trials for dermatomyositis. Photographs may be a useful tool for evaluating clinical trial patients in the future. More research is needed to determine innovations for improving our ability to evaluate skin activity through photographs such as the use of a color checker card or color correction algorithm.

279

The use of PRP to target dysregulated pathways in androgenetic alopecia

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Androgenetic alopecia (AGA) is the most common type of progressive hair loss; however, its treatment remains limited in scope, thus driving the need for alternative therapies for hair restoration. The pathogenesis of androgenetic alopecia is not completely understood but involves disruption of the Wnt/β-catenin signaling pathway, resulting in premature termination of the anagen growth phase in hair follicles. This manifests clinically as the transformation of terminal hair into thinner vellus-like hair, a process known as hair follicle miniaturization. Platelet rich plasma (PRP) has recently been regarded as a novel treatment for AGA. PRP is an autologous preparation of plasma that contains supraphysiologic concentrations of platelets and their associated growth factors, which have been implicated in regulating hair follicle growth. Nevertheless, the extensive variabilities in PRP preparation and administration protocols makes it difficult to interpret its clinical efficacy in treating AGA. This study follows a previous review from our group in 2018 by Cervantes et al. to analyze and discuss recent clinical trials which use PRP as treatment for AGA. We included those that assessed PRP in combination or in direct comparison with standard of care treatment for AGA, namely minoxidil and/or finasteride. We thoroughly examined and summarized the methodologies of fifteen original clinical trials published between 2018 and October 2021. Of the fifteen studies, five evaluated the combined and compared effects of PRP with standard treatment, seven established PRP as an effective treatment for AGA alone, and three concluded that PRP is ineffective in the treatment of AGA. By rigorously analyzing each clinical trial, we aim to provide an overall consensus on how PRP can be best used in the treatment of AGA.

280

A phase 2 randomized clinical trial of serlopitant, a neurokinin-1 receptor antagonist for the treatment of chronic itch in patients with epidermolysis bullosa

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Chronic itch is one of the most frequently reported symptoms in patients with epidermolysis bullosa (EB). We hypothesized that a neurokinin-1 receptor antagonist (NK1RA) which targets the substance P pathway can reduce EB-related itch. In 2019, we reported on the safety of a NK1R antagonist, serlopitant, in a pilot study. Here we report the phase 2 randomized, double-blind, placebo-controlled trial evaluating serlopitant 5mg PO daily for 8 weeks versus placebo for EB-related pruritus. The double-blind phase was followed by a 4-week washout and optional open label extension. Key inclusion criteria included age ≥13 yr, chronic itch lasting ≥6 wks and average 24-hour itch numerical rating scale (NRS) ≥5 at screening. The primary endpoint was the proportion of patients who achieved at least 3-point reduction in an 11-point NRS from baseline at 8 weeks as measured by daily NRS itch diaries. We enrolled 24 patients with a stratified randomization strategy to ensure equal distribution of participants with more severe EB subtypes. Two patients discontinued for non-compliance (n=1) and LFT elevation (n=1). Treatment arms were balanced in terms of EB subtypes and baseline itch; the mean (SD) of NRS was 5.3 (±2.2) in the placebo and 6.3 (±2.4) in the serlopitant group with the placebo group trending towards being older (mean 40.8 yo vs. 30.8 yo). At 8 weeks, 25% (n=3) of patients in the serlopitant group achieved at least a 3-point reduction compared with 8.3% (n=1) of placebo-treated patients although it was not statistically significance (p=0.59). In a linear mixed model analysis, the serlopitant group showed more NRS reduction relative to placebo (-0.64 point, p=0.16) at 8 weeks. No treatment-related serious adverse events were reported. This early phase study did not identify superiority of serlopitant but provides the basis for future studies in this rare disease.

281

Antenatal vitamin D supplementation & offspring risk of atopic eczema in infancy

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Observational studies have led to speculation that antenatal vitamin D supplementation may reduce the risk of offspring atopic eczema, but currently there are no proven general population preventive interventions. In the Maternal Vitamin D Osteoporosis Study double-blind, randomized, placebo-controlled trial, we examined the link between maternal supplementation (from 14 weeks' gestation until delivery) with cholecalciferol 1000 IU/day or matched placebo with offspring atopic eczema risk at age 12 months (n=636), ascertained based on the UK Working Party Criteria for the Definition of Atopic Dermatitis. Mothers and offspring characteristics did not differ between the intervention and placebo groups with the exception of longer breast feeding duration in the intervention group. The offspring of mothers who received 1000 IU cholecalciferol had lower odds ratios (OR) of atopic eczema at age 12 months: OR (95%CI) 0.57 (0.33-0.98), p=0.04. Sensitivity analysis stratified by breastfeeding duration demonstrated a reduced risk of atopic eczema in the intervention group in infants who were breastfed for more than 1 month (OR 0.48 (0.24,0.94), p=0.03), but not in those breastfed for less than one month (OR 0.80 (0.29,2.17), p=0.66); however, interaction terms between intervention and breastfeeding duration were not statistically significant (p=0.41). Our data provide the first randomized controlled trial evidence of a protective effect of antenatal cholecalciferol supplementation on risk of infantile atopic eczema, with the effect only seen in infants that were breastfed for more than 1 month. The findings support a developmental influence on atopic eczema, and point to a potentially modifiable perinatal influences on atopic eczema.

282

Modulation of inflammatory proteins in blood may reflect cutaneous immune responses in topical cancer immunotherapy

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Diphencyprone (DPCP), a hapten that causes delayed-type hypersensitivity reactions, has shown up to 84% efficacy in treating cutaneous metastases in melanoma patients. While a transcriptomic analysis of skin biopsies from melanoma metastases treated with topical DPCP revealed increases in Th1-related genes, a serum proteomic analysis of these patients has not yet been done. We evaluated the serum proteome of five patients with cutaneous melanoma metastases treated with DPCP twice weekly until day 112, assessing 96 proteins using the Olink immuno-oncology panel. All patients had at least partial regression of skin metastases. There was significant upregulation of proteins associated with promoting tumor immunity (TNFRSF4, TNFRSF9, CD83) and vascular/tissue remodeling (MMP12, PGF, ADGRG1) (P<0.05) upon DPCP treatment. Among the T-cell subsets, there was a significantly upregulated Th1 response (CXCL9, CXCL10, IL12) that progressively increased from day 63 to 112, when compared to day 0 (P<0.05). However, there was only a significant upregulation in Th2 (IL33) and Th17 (CCL20) markers on day 63 (P<0.05), but not day 112, in line with prior gene expression studies on skin samples. There was also significant and progressive upregulation of PD1 at both days 63 and 112 (P<0.05). This study is the first to assess serum protein biomarkers of patients with cutaneous melanoma metastases following topical immunotherapy. Topical DPCP led to an increase in systemic markers of immune activation, particularly the Th1 axis, which has previously been shown in skin and correlates with tumor regression. Additionally, we observed an increase in PD1, which is of great clinical relevance as inhibitors of this receptor are currently standard-of-care treatment for melanoma. Our data suggest potential synergy between DPCP and PD1 checkpoint inhibition as a future cancer therapy regimen for patients with cutaneous melanoma metastases.

283

Photodynamic therapy for basal cell carcinoma enhanced by pretreatment with oral vitamin D: interim results of a prospective clinical trial

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Photodynamic therapy (PDT) is used in Europe to treat basal cell carcinoma (BCC), but it is not approved in the USA due to uncertainties about efficacy. Vitamin D3 (VD3; cholecalciferol) treatment prior to PDT improves BCC responses in mice. A prospective, double-blind, crossover clinical trial [NCT03467789] was designed to test whether oral VD3 pretreatment enhances BCC response to blue light PDT. Participants received 3 PDT treatments (20% ALA, 4 h; 417 nm, 30 min) 2 months apart. High-dose VD3 or placebo was administered prior to each of the first two PDT sessions. Lesions were recorded with a 3D digital camera to allow software-assisted tumor volume analysis. Treatment-resistant tumors were biopsied at the final visit. To date, 24 patients and 128 BCCs have been analyzed. Two-thirds (70%) of all lesions cleared completely after PDT. Of the 30% of tumors that failed to clear, all except one superficial BCC were either nodular, micronodular, adenoid, or infiltrative subtypes. To assess the ability of neoadjuvant VD3 to potentiate PDT efficacy, we evaluated all available lesions to determine their relative volume reduction after VD3+PDT and placebo+PDT. Tumors that fulfilled a prediction that shrinkage (% volume reduction) would be greater after VD3+PDT compared to placebo+PDT were scored as "Yes". In our analysis, 15 patients scored "Yes" and 6 scored "No". This >2-fold difference provides preliminary evidence that neoadjuvant VD3 augments therapeutic responsiveness to PDT for many BCC tumors. PDT may be an effective treatment for BCC, especially superficial BCC. Oral VD3 given prior to PDT represents a novel and safe combination approach.