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Dupilumab significantly improves sleep disturbance in adults with moderate-to-severe atopic dermatitis: Results of the DUPISTAD study



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Background: Sleep disturbance, a prominent symptom of atopic dermatitis (AD), primarily related to nighttime itching/scratching, leads to insomnia, daytime fatigue/drowsiness, reduced productivity, and impaired quality of life. The DUPISTAD phase-IV randomized double-blinded placebo-controlled study (NCT04033367) evaluated the impact of dupilumab on sleep.

Methods: Adults with moderate-to-severe AD (Eczema Area and Severity Index [EASI] ≥ 12 , Pruritus numerical rating scale (NRS) ≥ 3 and sleep NRS ≥ 5) were randomized 2:1 to dupilumab 300 mg every 2 weeks (q2w) or placebo for 12 weeks (W12); both groups were permitted concomitant topical corticosteroids. The primary efficacy endpoint was sleep quality percentage change from baseline to W12, assessed by 11-point sleep NRS. Secondary endpoints included percent change in peak pruritus NRS, change in SCORing AD (SCORAD), SCORAD sleep visual analog scale (VAS), EASI and the Patient-Reported Outcomes Measurement Information System sleep-impairment SF8a score (PROMIS-T).

Results: 127 patients received dupilumab 300 mg q2w and 61 placebo. Mean baseline SCORAD was 64.7 vs. 62.9, and EASI 26.2 vs 26.0 in the dupilumab and placebo groups, respectively. Sleep NRS significantly improved in dupilumab-treated patients at W12 vs. placebo (least squares mean difference [LSMD] -15.1%; $P < .001$). Peak pruritus NRS (LSMD -28.6%, $P < .001$), SCORAD (LSM -14.4, $P < .001$), SCORAD sleep VAS (LSMD -2.3, $P < .001$), and PROMIS-T Score (LSMD -3.6, $P = .001$), also improved significantly with dupilumab vs. placebo. Treatment-emergent adverse events (TEAE) occurred in 52.8% in the dupilumab group vs. 62.3% with placebo. Four TEAEs (dupilumab: 3 [2.4%]; placebo: 1 [1.6]%) resulted in study discontinuation.

Conclusion: Dupilumab significantly improved sleep, itch and total SCORAD in adults with moderate-to-severe AD.

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33004

Dupilumab significantly reduces itch and hives in patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite use of standard-of-care antihistamines: Results from a phase 3 trial (LIBERTY-CSU CUPID study A)



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Background: CSU causes recurrent itchy wheals and/or angioedema, significantly impacting quality of life. Many patients experience substantial disease burden despite treatment with standard-of-care H1 antihistamines.

Methods: LIBERTY-CSU CUPID study A (NCT04180488), a randomized, placebo-controlled, 24-week, phase 3 trial evaluated dupilumab efficacy and safety in patients aged ≥ 6 years with CSU who remained symptomatic despite treatment with antihistamines. Patients on a standard or ≤ 4 -fold dose of antihistamines were randomized to receive add-on dupilumab ($n = 70$) 300 mg (adults/adolescents ≥ 60 kg) or 200 mg (adolescents < 60 kg/children ≥ 30 kg), or matching placebo ($n = 68$) subcutaneously every 2 weeks. Primary and key secondary endpoints included change from baseline at Week 24 in Itch Severity Score over 7 days (ISS7) and Urticaria Activity Score over 7 days (UAS7). Other secondary endpoints included change from baseline at Week 24 in Hive Severity Score over 7 days (HSS7).

Results: Baseline characteristics were generally balanced across treatment groups. Mean ISS7, UAS7, and HSS7 (dupilumab/placebo) at baseline were: 15.7/16.1, 30.8/31.9, and 15.0/15.8, respectively. At Week 24, least squares (LS) mean change in ISS7 (range:0–21) from baseline was -10.2/-6.0 for dupilumab/placebo, respectively (LS mean difference -4.2, $P = .0005$); UAS7 (range:0-42): -20.5/-12.0 (difference -8.5, $P = .0003$); HSS7 (range:0–21): -10.3/-5.9 (difference -4.4, $P = .0003$). Overall treatment-emergent adverse events (TEAEs) were comparable between dupilumab and placebo: 35 (50.0%)/40 (58.8%); occurrence of injection site reactions was 8 (11.4%)/9 (13.2%), conjunctivitis 0/1 (1.5%), and serious TEAEs 2 (2.9%)/5 (7.4%).

Conclusion: Dupilumab demonstrated clinically meaningful and statistically significant improvements in patients with antihistamine-resistant CSU and was well tolerated.

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Duration and recurrence of pityriasis rosea-like reactions following COVID-19 vaccination: A registry based study of 27 cases



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Pityriasis rosea-like (PR-like) reactions have been reported after COVID-19 vaccination, however studies describing duration are lacking. Using the AAD/ILDS COVID-19 dermatology registry we analyzed patients with pityriasis rosea-like reactions after COVID-19 vaccination, including those classified in the newly defined V-REPP spectrum. Patients were 56% female with median age 45 (IQR 33-59). Vaccine brands were Moderna (51%), Pfizer-BioNTech (33%), Oxford-AstraZeneca (7.4%), Johnson and Johnson (3.7%), and CoronaVac (3.7%). Reports included reactions after the first dose ($n = 14$, 52%), second dose ($n = 8$, 30%), and both doses ($n = 5$, 18%). Reactions were ongoing at time of reporting for 79% of first dose reactions and 85% of second dose reactions. For records where complete duration of PR-like reaction was known, median duration of first dose reaction was 66 days (IQR 32-111). For records where the PR-like rash was ongoing, duration of first dose reaction was 23 days (IQR 10-35). In records where complete duration of PR-like reaction was known for the second dose, median duration was 85 days (IQR 70-100). For records where the PR-like rash was ongoing after the second dose, duration was 14 days (IQR 14-30). For patients where information was available for both vaccine doses ($n = 12$), 42% had a flare of the PR-like rash with the second vaccine dose. In summary, PR-like reactions following COVID-19 vaccination often last for more than one month, with some lasting several months. Flares are common with second vaccine dose, leading to speculation of future PR-like flares with the newly approved COVID-19 vaccine boosters.

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33696

Dyschromatosis symmetrica hereditaria disguised as lentiginos



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Background: Dyschromatosis symmetrica hereditaria (DSH) is rare autosomal dominant (AD) pigmentary disorder consisting of reticulated patches of hypopigmentation and hyperpigmentation on the hands and feet. It is seen predominantly in patients of Asian ancestry. Adenosine deaminase acting on RNA 1 (ADARI) is the mutation. DSH has been reported to coexist in patients with Aicardi-Goutières syndrome (AGS), intellectual disability, and dystonia. Here we present a case of a patient likely representing a de novo mutation of DSH.

Observation: A 14-year-old boy of Chinese ancestry presented for asymptomatic dark spots located on the backs of the hands. On examination, there were multiple brown macules limited to the dorsum of the hands and feet with a sharp line of demarcation at the wrist and ankles. The differential at the time included multiple lentiginos syndrome and Carney complex; however, upon further evaluation, patchy areas of hypopigmentation located on the dorsal hands, ankles, and feet were noted. A diagnosis of DSH was rendered. The patient was subsequently referred for genetic testing.

Comments: DSH, a rare AD disorder, remains a clinical diagnosis; however, a biopsy could be used to confirm the diagnosis. DSH is caused by a mutation in ADARI. Mutations have been associated with nervous system disorders, tumorigenesis and AGS, which is a rare inflammatory and neurological disorder. Given the neurological associations with DSH, it is important the condition is recognized early and patients are sent for genetic testing due to the potential ramifications for offspring.

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