MICRO LABS LIMITED

# DERMA TODAY

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Dear Doctor,

Greetings from Micro Labs. We are happy to bring you "Derma Today" which contains latest and interesting news in the field of Dermatology.

This issue contains:

1. Omalizumab in severe paediatric atopic dermatitis.
2. Today's Pick: Prognostic factors in mucosal melanoma

Should you require any article or, medical information, please feel free to contact us medicalservices@microlabs.in

Looking forward to your valuable feedback.

Best Regards,

Medical Team, Micro Labs Limited.

# Omalizumab in severe paediatric atopic dermatitis.

Systemic therapy in children suffering from severe atopic dermatitis have very limited evidence. Though Omalizumab (anti-IgE) is used in the treatment of atopy, there has not been any large randomized study suggesting it's usage in childhood atopic dermatitis.

## Aim:

The study was undertaken to ascertain the efficacy of Systemic Omalizumab in treatment of severe atopic dermatitis amongst children.

## Design, setting, and participants:

The Atopic Dermatitis Anti-IgE Pediatric Trial or, ADAPT was a conducted over 24-weeks in a single-center. The study had double-blinding. It had placebo as control. It was a randomized clinical trial with 24-week follow-up which was conducted from November 20, 2014, to August 31, 2017, at Guy's and St Thomas' Hospital NHS Foundation Trust and King's College London in the United Kingdom.

In this trial participants were recruited after an initial screening visit. Total of 62 eligible participants who were aged between 4 & 19 years and were diagnosed with severe eczema (with objective Scoring Atopic Dermatitis [SCORAD] index >40) which did not respond to optimum therapy, were enrolled. Statistical analysis was done by using the intention-to-treat principle.

## INTERVENTIONS:

Subcutaneous omalizumab or placebo was administered for 24 weeks. The dosing was determined via drug manufacturer's dosing tables based on total IgE (30-1500 IU/mL) and body weight (in kilograms) at the time of randomization.

## MAIN OUTCOMES AND MEASURES:

Objective SCORAD index after 24 weeks of treatment.

## RESULTS:

The total enrolled 62 children (mean age, 10.3 years; 32 (52%) male) were randomized to either omalizumab group or placebo group. The Omalizumab group comprised of 30 candidates & the placebo group comprised of 32 children.

5 participants withdrew (4 from the placebo group, and 1 from the omalizumab group).

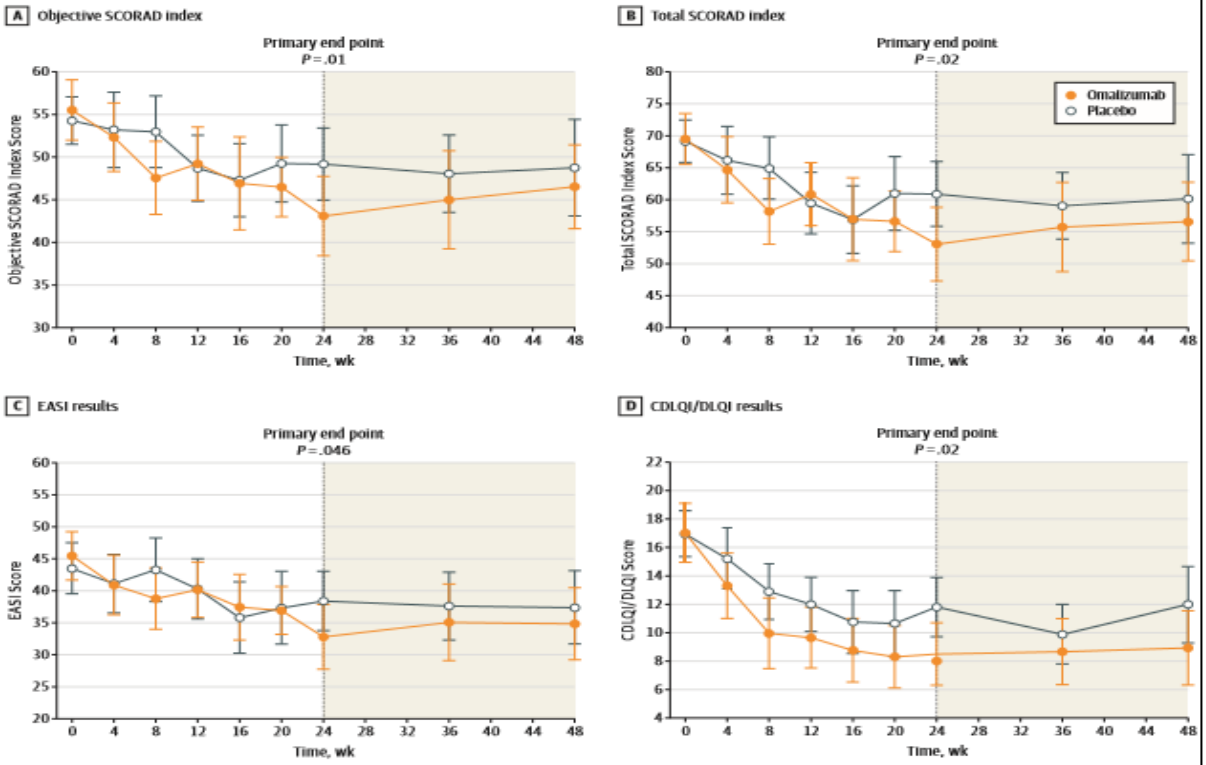
After adjustment for baseline objective SCORAD index, age, and IgE level, the mean difference in objective SCORAD index improvement between groups at week 24 was −6.9 (95% CI, −12.2 to −1.5; P = .01).

It was significantly in favour of omalizumab therapy. It was similarly reflected in the results in other assessments of atopic dermatitis severity.

Improved quality-of-life scores were seen in the omalizumab group(Children's Dermatology Life Quality Index/Dermatology Life Quality Index) and Pediatric Allergic Disease Quality of Life Questionnaire score.

There was improvements in severity of the disease despite use of lower potential topical corticosteroid in the omalizumab group as compared to the placebo group.

**Atopic Dermatitis Severity and Quality of Life in Participants During the 24-Week Treatment and 48-Week Follow-up Periods**




CDLQI/DLQI indicates Children's Dermatology Life Quality Index/Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; and SCORAD, Scoring Atopic Dermatitis.

**Change in Eczema Severity Scores From Baseline to Week 24**

| Outcome | Mean (SD) | | | | | | Adjusted Mean Difference: Omalizumab – Placebo (95% CI)[a] |
|---|---|---|---|---|---|---|---|
| | Omalizumab | | | Placebo | | | |
| | Baseline (n = 30) | Week 24 (n = 30) | 24-wk Change (n = 30) | Baseline (n = 32) | Week 24 (n = 30) | 24-wk Change (n = 30) | |
| Objective SCORAD index (MCID: 8.5) | 55.5 (9.5) | 43.1 (12.5) | −12.4 (12.1)[b] | 54.3 (7.7) | 49.2 (11.3) | −5.1 (11.7) | −6.9 (−12.2 to −1.5) |
| Total SCORAD index (MCID: 8.7) | 69.5 (10.7) | 53.1 (15.4) | −16.4 (17.0)[b] | 69.1 (9.2) | 60.9 (13.5) | −8.6 (13.6) | −8.3 (−15.1 to −1.1) |
| EASI score (MCID: 6.6) | 45.5 (10.1) | 32.8 (13.5) | −12.7 (15.2)[b] | 43.5 (11.1) | 38.4 (12.4) | −4.9 (13.5) | −6.7 (−13.2 to −0.1)[b] |

Abbreviations: EASI, Eczema Area and Severity Index; MCID, minimum clinically important difference; SCORAD, Scoring Atopic Dermatitis.

[a] Adjusted for baseline value of the outcome, serum IgE level (≤1500 or >1500 IU/mL [to convert to milligrams per liter, multiply by 0.0024]) and age (<10 or ≥10 years).

[b] Exceeds the minimum clinically important difference.

## CONCLUSIONS AND RELEVANCE:

This trial found systemic omalizumab to significantly reduce the severity of atopic dermatitis and improve quality of life in a pediatric patient with severe eczema despite having elevated total IgE levels at onset.

Omalizumab may be a treatment option for difficult-to-manage severe eczema in paediatric patients.

Chan S. et al. JAMA pediatrics. 2020 Jan 1;174(1):29-37.

# Today's Pick

# Prognostic factors in mucosal melanoma.

161 patients with mucosal melanoma were studied prospectively. It was reported in the German Central Malignant Melanoma Registry. This was conducted to find out the risk factors which influence the course of the disease & prognosis of patients who are suffering from this disease condition.

The patients were grouped as 44.7% oral–nasal, 28.6% genital, 20.5% anorectal and 6.2% visceral. This classification was based on the localization of the melanoma.

Amongst all the groups, the most favourable 5-year overall survival (OS) rate was noted in genital mucosal melanomas which was about 58.6%. This was followed by visceral melanoma which had a 5-year overall survival (OS) rate as 58.3%. Oral–nasal melanoma exhibited a 5-year overall survival (OS) rate as 39.3%.

The worst 5-year overall survival (OS) rate time (median: 21 ± 4.8 months) and 5-year survival rate (22.7%) was seen in anorectal melanomas. Better survival is noted in patients younger than 60 years compared to those who are older.

The stage of tumour at the time of the first detection was found to be crucial in influencing survival. Survival was seen to be negatively influenced by old age and advanced stage of the disease.

Thus, AJCC staging system was concluded as applicable in case of mucosal melanoma.

Sarac E. et al. Journal of the European Academy of Dermatology and Venereology. 2020 Feb 20.