

## Clinical trial recommends methotrexate for children with severe atopic dermatitis

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Atopic dermatitis. Credit: <u>AfroBrazilian</u>/Wikimedia Commons, <u>CC BY-SA</u>

A study led by King's College London compared the safety and efficacy



of ciclosporin with methotrexate in children and young people with severe atopic dermatitis, a debilitating skin condition. They also examined whether the severity of the disease changed or returned after treatment ended.

For <u>children</u> and young people with <u>atopic dermatitis</u>, the most common skin condition in children, the main first line conventional systemic treatments are <u>methotrexate</u> and ciclosporin, two immuno-modulatory drugs.

However, until now there has been no adequately powered randomized clinical trial evidence in relation to their <u>safety</u> and <u>treatment success</u> for pediatric patients with this condition, and with new therapies being introduced at a high cost, establishing a gold standard for treatment with the conventional systemic therapies like methotrexate and ciclosporin is needed.

The trial assessed 103 children with severe atopic dermatitis age 2–16 years across 13 centers in the U.K. and Ireland. The patients were given oral doses of methotrexate or ciclosporin and assessed over nine months of treatment and six months after the therapy ended.

The study found that ciclosporin works faster and reduces disease severity more at 12 weeks but was more expensive, whereas methotrexate was significantly cheaper and led to better objective disease control after 12 weeks and off therapy, with fewer participant-reported flares of atopic dermatitis after treatment had stopped. There were also no concerning safety signals.

The paper, "Efficacy and safety of ciclosporin versus methotrexate in the treatment of severe atopic dermatitis in children and <u>young people</u> (TREAT): a multicentre, parallel group, assessor-blinded clinical trial," is published in the <u>British Journal of Dermatology</u>.



Based on the trial findings, methotrexate is a useful and safe treatment in pediatric patients with severe atopic dermatitis and a good alternative to ciclosporin, especially in settings where health care resources are limited.

"This is the largest pediatric trial using conventional immunomodulatory treatments in severe atopic dermatitis and was conducted across 13 centers in the U.K. and Ireland and is likely to change our treatment paradigm around this condition, not just for patients in the U.K. but also internationally," says Professor Carsten Flohr.

**More information:** Carsten Flohr et al, Efficacy and safety of ciclosporin versus methotrexate in the treatment of severe atopic dermatitis in children and young people (TREAT): a multicentre, parallel group, assessor-blinded clinical trial, *British Journal of Dermatology* (2023). DOI: 10.1093/bjd/ljad281

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