Prof. Sigurgeirsson, principal investigator of Petite Study

Meet the Principal Investigator

Professor Bardur Sigurgeirsson

Bardur Sigurgeirsson is an Adjunct Professor at the Faculty of Medicine, Department of Dermatology, University of Iceland. He is a dermatologist with a long and distinguished career ranging from leading basic scientific research to teaching, patient care and clinical research. His main research interests include AD, psoriasis, onychomycosis and malignant melanoma. He has co-authored more than 80 publications in his fields of expertise.

Why is the Petite study so important?

The Petite study was the first long-term direct comparative study of Elidel® and TCS for the treatment of patients with mild-to-moderate AD. Prior to this study, Elidel® was considered to be less effective at treating AD than low to medium potency TCS. The Petite study was also important in providing long-term safety data on the use of Elidel® and examining its effect on the developing immune system. Given that the Petite study randomised 2439 patients with AD from countries around the world and followed them for the first five to six years of life, we now have compelling data on the comparative efficacy and safety of Elidel® and TCS.

> **"The Petite study was the first long-term direct comparative study of Elidel® and TCS for the treatment of patients with mild-to-moderate AD and was also important in providing long-term safety data on the use of Elidel®"**

What would you say are the key Findings of the Petite study?

For me, there were three key Findings from the Petite study. Firstly, the Petite study showed for the first-time that Elidel® and TCS are equally effective in treating mild-to-moderate AD. Secondly, Elidel® was associated with a substantial steroid-sparing effect. Thirdly, long-term management of AD with both Elidel® and TCS was well tolerated without any impact on the developing immune system.

What is the clinical significance of Elidel® and TCS having equal efficacy?

The current label for Elidel® in the EU restricts its use to patients aged 2 years and older and to use when treatment with TCS is inadvisable or not possible, e.g. on sensitive skin areas. The Petite study demonstrates the clinical efficacy and favourable safety profile of Elidel® in patients younger than two years. The similar efficacy of Elidel® and TCS indicates that Elidel® should be considered as first-line treatment of mild-to-moderate AD, and so should not be reserved for second-line use or use on sensitive skin areas.

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Why is the steroid-sparing effect of Elidel® important?

The steroid-sparing effect of Elidel® shows that mild-to-moderate AD can be treated with a non-corticosteroid alternative, which does not expose patients to the potential side effects associated with long-term TCS use such as skin atrophy and an increased risk of infections. Currently, one out of every three patients treated with TCS are not compliant due to corticophobia, resulting from factors such as fear of their potential side effects. The steroid-sparing effect of Elidel® may help to improve treatment compliance, although this was not specifically evaluated in the Petite study. The reduced steroid requirement may also be beneficial in terms of reducing the overall steroid burden for patients with atopic co-morbidities such as asthma and allergic rhinitis which also need to be treated with steroids.

What do the safety findings from the Petite study tell us?

The comprehensive real-world safety data collected in the Petite study convincingly demonstrates that the long-term management of mild-to-moderate AD with Elidel® is well tolerated with no impact on the developing immune system. The latter was evaluated given concerns that the immunomodulatory mode of action of Elidel® could theoretically affect the immune system, but this was not the case. There was no evidence that Elidel® leads to systemic immunosuppression over five years of use and no patient developed lymphoma or skin cancer. The safety findings are both compelling and important. Currently, Elidel® is not indicated for use in infants in Europe and there is a black box warning on the US label highlighting that its long-term safety has not been established, that there is a theoretical risk of malignancy and emphasising that Elidel® is not suitable for use in children less than 2 years of age. The Petite study further adds to the growing body of clinical, epidemiological and post-marketing surveillance data supporting the long-term safety of Elidel®, and the need for regulatory agencies to re-evaluate the labelling restrictions currently in place.

What are the main problems associated with the use of TCS for the treatment of AD?

Long-term use of TCS can lead to side effects such as skin atrophy, an increased risk of infections, and percutaneous absorption possibly leading to impaired growth. Many patients and their caregivers are afraid of using TCS, resulting in approximately one-third being non-compliant with their treatment. Furthermore, the long-term safety of individual TCS have not been evaluated and their use is restricted to four weeks or less depending on the specific TCS and its country-specific label.

In your opinion, what impact should the results of the Petite study have on the clinical management of AD?

In my opinion, the Petite study should lead to a paradigm shift in the way that mild-to-moderate AD is treated. The efficacy and safety data obtained in this study provide a compelling argument for using Elidel® as a first-line treatment alternative in these patients. I also sincerely hope that the current restrictions regarding the use of Elidel® in infants are revoked allowing these patients access to a treatment option with proven long-term efficacy and favourable safety profile.

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