Study Protocol, Statistical Analysis Plan, and/or Informed Consent

Title

Treatment of Ocular Surface Inflammations With 1% Cyclosporine (Ikervis) Eye Drops

Organisation

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Study's Unique Protocol ID

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Brief Description

Background

The treatment of ocular surface inflammations requires a high level of expertise, particularly in cases lasting more than three weeks, which carry a risk of morphological deterioration of the ocular surface structure and function.

This applies to chronic allergic ocular inflammation and blepharokeratoconjunctivitis. Patients treated with topical cyclosporin 0.1% showed a significant improvement in all subjective symptoms and objective signs, and the total number of courses of rescue steroids courses decreased from baseline to 3- and 6 months follow-up (*Barcsay-Veres A et al, Scientific Reports, 2025*). Topical cyclosporin seems to be very effective reducing the number of recurrences of corneal involvement and the need for steroid treatment. Chronic ocular inflammation is often combined with dry eye disease. Dry eye is a multifactorial, symptomatic disease characterized by a loss of homeostasis of the tear film and/or ocular surface, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities are etiological factors (*DEWS III, Am J Ophthalmol 2025*). The morphological characteristics of the meibomian glands (MG) in children with allergic conjunctivitis feature differences between allergic ocular inflammation children with dry eye and healthy children. Detailed grading of MG morphology provide evidence that tortuous or distorted MGs in

the eyelids were obviously more common in allergic dry eye children than in healthy children (*Xiao-Jiao Tang et al. J Asthma Allergy 2025*).

Aim

The aim of this study is to evaluate the underlying processes of the aforementioned clinical entities, particularly in the paediatric population, and to identify the advantages and disadvantages of treatment with 1% cyclosporine eye drops.

Design and Methods

Prospective observational study involving patients with chronic allergic ocular inflammation and blepharokeratoconjunctivitis from all genders and rasses. Inclusion criteria is minimum age of 4 and maximum age of 60 years. Regular ophthalmological visits every 3 months measuring subjective symptoms and objective signs of ocular inflammation and dry eye.

Ocular surface indicators (such as ocular surface staining (Oxford grading), tear break-up time, tear film lipid layer, etc.) and MG morphology using infrared meibography serve the purpose to find the relationship with the pathogenesis of inflammatory processes and related dry eye and ocular surface deterioration.

Statistical Analysis Plan: data analyses will be performed using R software (R Core Team, Vienna Austria). Specific characteristics of the meibomian glands and the other ocular surface descriptors and subjective symptom points will be quantified using odds ratio with the corresponding 95% confidence intervals. Mixed models will be applied to introduce age-group and diagnostic group interactions. Models including treatment status (baseline, on treatment, off treatment) as the primary predictor, with adjustments for time, cumulative drug exposure and age.

Informed Consent Form (ICF): The final version of the legal document approved by a human subjects protection review board. It is written in lay language and describes, among other things, the study’s purpose, procedures, risks and potential benefits. Uploaded separately.