Paediatric Vernal Keratoconjunctivitis – The VEKTIS Study

An Expert Interview with Dominique Bremond-Gignac

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Q. Could you tell us about vernal keratoconjunctivitis and its unmet needs?

Vernal keratoconjunctivitis (VKC) is a rare, but severe ocular disease which manifests from keratoconjunctivitis. VKC typically affects children between the ages of 3–17 years; however, the disease resolves in 90% of cases during adolescence.[1] Males are more affected than females (sex ratio 3:1).[1] VKC can be very severe, impacting quality of life, and can result in school dropout. Affected patients present with tearing, photophobia, mucous discharge, itching and visual impairment. There are two main classifications of VKC: tarsal, which presents with giant papillae of the eyelid; and limbal, which involves epithelial infiltrates called Horner-Trantas dots. A third, mixed variant also exists, but is rarely observed. As VKC is an allergic disease, other manifestations can be present, such as asthma, rhinitis and eczema in varying degrees of severity.

The management of VKC includes frequent washing of the hands and face, prescription of antihistamines and mast cell stabilisers. Until recently, however, the only validated available treatment for severe forms of VKC was steroids. Steroids are efficient, however, iatrogenesis is a common problem, leading to long-term treatment or steroid dependence, glaucoma, corneal herpes recurrence and cataracts; complications which may severely affect vision. The requirement for a different validated medication was urgent. Topical cyclosporine is used for its anti-inflammatory properties and is available in hospitals in different dosages. In order to demonstrate the safety and efficacy of cyclosporine in VKC, the VErnal KeratoconjunctiviTIs Study (VEKTIS) study was initiated.[2]

Q. What were the objectives of the VEKTIS study?

The VEKTIS study was devised to demonstrate the safety and efficacy of cyclosporine for VKC.[2] The objective also included steroid-sparing for affected children to avoid iatrogenicity caused by long-term treatment.

Q. How many patients were included in the VEKTIS study and how was the study designed?

One hundred and sixty-nine patients were included in the VEKTIS study, with a follow-up of 12 months. Of these, 143 patients completed the whole follow-up period.[2] Patients were randomised to one of three arms: a vehicle arm, a low-dose arm (twice a day) and a full-dose arm (four times a day).[2]

Q. What were the key efficacy and safety findings of the study?

Key efficacy was evaluated with a composite score that included Clinical Frailty Scale score, a corneal fluorescein staining score, the need for rescue medication, and the occurrence of corneal ulceration.[2] Safety was evaluated with the Quality of Life in Children with Vernal Keratoconjunctivitis questionnaire, and adverse events were reported.[2,3] Efficacy and safety were demonstrated in the study, showing superiority of the high-dose regimen.[2]

Q. Have any further studies been planned?

Further clinical studies have not yet been planned. Treatment guidelines for the disease may be reviewed and updated. However, further studies are needed to determine better treatment duration and other allergic keratoconjunctivitis forms. We are thinking of new study designs for the future.

Q. What do the VEKTIS study results mean for the management of vernal keratoconjunctivitis?

The VEKTIS study results are encouraging for the treatment of children with severe VKC and will make it easier for parents to manage the disease.

Physicians are always waiting for clinical studies to demonstrate the safety and efficacy of new pharmaceutical products, not only for VKC, but also in other severe, rare diseases. Published studies with satisfactory results give doctors the opportunity to prescribe eyedrops for VKC in line with recommendations.

For a long time, parents have been seeking eyedrops for their children that can be obtained from regular pharmacies. This will help parents to manage their children's disease more easily. Other positive observations from the study include improvements in keratitis, key VKC symptoms and a stable quality of life profile. ❑

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