

Immune Invitation to participate in Dry Eye study

The effect of 0.1% ciclosporin A eye drops for 12-weeks on immune cells at the surface of the eye in dry eyes

Researchers at UNSW are conducting a study to understand the effect of 0.1% ciclosporin A eye drops on immune cells at the surface of the eye in people with dry eyes.

All the study medications are approved by the Therapeutic Goods Administration (TGA) in Australia to treat Dry Eyes.

You are a potential participant for the study if

- You are above 18 years of age
- You have signs and symptoms of or have already been diagnosed with dry eye disease

You are not eligible to participate in the study if you meet any of the following conditions.

- You are currently using or have used any anti-inflammatory eye drops in the past 6 months.
- You are on oral ciclosporin or tacrolimus.
- You have known allergy to the study medication.
- You have an active eye disease inside the eye.
- You are a regular contact lens user or have used contact lenses in the last 4 weeks.
- You have an active eye infection or critical illness.
- You have dry eyes due to Steven-Johnson syndrome, cicatricial conjunctival disease.
- You have other eye conditions or use eyedrops for glaucoma.
- You have a history of eye surgery in the past 6 months.
- You are pregnant or breastfeeding.



Participants will be asked to complete dry eye tests and follow-up visits, if they agree to participate

- Telephone and paper-based questionnaires will take approximately 2 minutes to complete.
- **The study involves 4 visits: Visit 1: screening for eligibility (dry eye tests) and start 2-weeks wash-out period.**

Visit 2: at 2-weeks – dry eye tests, confocal microscopy, tear and cell collection. You will enter either into one of the two treatment arms.

Group A – Ciclosporin A (CsA) 0.1% once daily at night-time + Cationorm four times daily in both eyes for 12-weeks.

Group B – Cationorm four times daily in both eyes for 12-weeks.

Visit 3: at 6-weeks – dry eye tests and confocal microscopy.

Visit 4: at 14-weeks - dry eye tests, confocal microscopy, tear and cell collection.

- A full description of all research activities, including any risks, or discomforts that you may experience while participating in this research is included in the attached Participant Information Statement and Consent Form.

Please contact the following person via email or phone to register your interest and for more details:

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If you have questions about the research and would like to contact the Chief Investigator, please contact the following person:

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