

Open Label Trial Studying the Safety and Effectiveness of ILUVIEN® (19004) in Children and Adolescents, Who Have Recurrent Non-infectious Uveitis Affecting the Posterior Segment of the Eye.

NCT06539481

Status	RECRUITING
Phase	Phase 4
Sponsor	Alimera Sciences
Enrollment	25 participants

Key Eligibility Criteria

Inclusion (4)

- Males and females of e6 and \<18 years of age at time of consent
- Non-infectious posterior, intermediate or panuveitis in the study eye with a history of recurrence e1 per year as assessed by the Investigator
- Uveitis in the study eye not adequately controlled by the preferred standard of care due to intolerable adverse effects or poor response, in the judgment of the Investigator
- Treatment with systemic corticosteroid or other systemic therapies given for at least 3 months within the previous 12 months prior to Day 1

Exclusion (4)

- History of intraocular surgery in the study eye within 90 days of the screening visit.
- Hypersensitivity to FA or any component of ILUVIEN®
- History of any form of glaucoma or ocular hypertension in study eye, unless study eye has been previously treated with an incisional IOP-lowering surgical procedure at least 90 days prior to the screening visit and that procedure has resulted in stable IOP in the normal range (10-21 mmHg)
- Increased intraocular pressure \>25 mmHg or that required treatment including increases in medications, surgery (other than drainage surgery), or hospitalisations, within 4 weeks prior to baseline that, in the opinion of the Investigator, would pose an unacceptable risk to the patient participating in the study

Locations (6 total)

Charité - Universitätsmedizin Berlin Institute of Health Department of Ophthalmology, Berlin, Germany
Augenzentrum am St. Franziskus-Hospital Münster, Münster, Germany
Hospital Universitario Cruces, Bilbao, Spain
... and 3 more locations

<https://clinicaltrials.gov/study/NCT06539481>

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