

# Clinical Investigation Between the Topical Administration of a Tear Substitute With Ancillary Medicinal Substance and Hyaluronic Acid 0.3% (FBV\_01) vs Hyaluronic Acid 0.3% in Subjects in the Treatment From Moderate to Severe DED

NCT07412860

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Status	RECRUITING
Phase	Not Applicable
Sponsor	FB Vision S.p.A
Enrollment	74 participants

## Key Eligibility Criteria

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### Inclusion (11)

- Patients able to provide written Informed Consent, in accordance with good clinical practice and current legislation;
- Patients (male and female) 18 years of age or older with moderate to severe dry eye syndrome or with dry eye syndrome, even after eye surgery (e.g. refractive surgery or cataract);
- Moderate to severe dry eye syndrome in one or both eyes in the presence of:
- Dry Eye Symptom Assessment Questionnaire (SANDE)  $\geq 60$ ;
- Tear Film Break-Up Time (TFBUT)  $< 7$  seconds. TFBUT value will be recorded as an average of 3 measurements;
- ... and 6 more (see full listing online)

### Exclusion (17)

- Eye infection or clinically significant inflammation in both eyes (for example: Herpes simplex infections, corneal virus infections, bacterial, viral or fungal conjunctivitis, tuberculosis and mycosis of the eye, purulent and herpetic blepharitis, stye);
- History or evidence of eyelid abnormalities in either eye;
- Use of topical cyclosporine, topical corticosteroids, or any other topical medication for the treatment of ocular pathologies in either eye within 7 days of study enrollment;
- Patients being treated with chronic systemic therapies with analgesic, anti-inflammatory, corticosteroids, or opioids;
- History of ocular surgery (including laser procedures or refractive surgery) in either eye 7 days prior to enrollment;
- ... and 12 more (see full listing online)

## Locations (2 total)

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S.C. di Oculistica Azienda Ospedaliero-Universitaria di Cagliari Presidio San Giovanni di Dio, Cagliari, CA, Italy  
U.O. Oculistica Azienda Ospedaliero-Universitaria Renato Dulbecco, Catanzaro, CZ, Italy