ISRCTN32614942 https://doi.org/10.1186/ISRCTN32614942

A trial looking at the safety of a fluid-gel eyedrop containing blood serum in patients with dry eyes

Submission date 13/12/2022	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/08/2023	**Overall study status** Stopped	
Last Edited 17/11/2026	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Ocular surface disease (OSD) is a cause of eye discomfort. It is a complex condition that includes severe dry eye disease (DED). Symptoms such as dryness and eye pain can lead to anxiety, and these can affect sight and well-being. Lubricating eye drops are used to relieve symptoms but these need to be applied frequently and their effects can be short-lived. The University of Birmingham has developed a new fluid-gel eyedrop containing blood serum (a standard treatment for severe OSD) which may stay on the eye surface for longer than current lubricating eye drops, thereby providing longer-term relief. Phase I and II trials are done with a small number of people to see if an experimental treatment is safe. The eyedrops are made of products currently in other eyedrop treatments used in clinical practice. The main aim of this trial is to investigate whether the gel-based eyedrop, alone (called FLG-1001) or containing serum (called FLG-SED1) can be applied safely to eyes. Whether the gel-based eyedrops are better at providing patient comfort by improving eye surface health more than the standard treatment, serum in saline (called ATF-Allo-SED in this study), will also be studied.

Who can participate?
Participants aged 16 years old and over with moderate to severe DED who have used or are currently using serum eye drops

What does the study involve?
This trial has two stages. In Stage 1, six DED patients will receive each treatment for one day over three consecutive days. In Stage 2, 30 DED patients will be given (at random) either FLG-1001, FLG-SED-1 or ATF-Allo-SED for 42 days, followed by one extra visit one-week later. Safety will be measured by looking at how the treatments affect the eye surface and patient symptoms using clinical tests, patient diaries and questionnaires. Patients will use their current eye medication alongside the new treatments if needed.

What are the possible benefits and risks of participating?
The possible benefits of participating:
1. The new fluid-gel eye drops may improve DED symptoms

2. Participants may experience longer periods of eye comfort and therefore it may mean they won't need to use their other treatments as often
3. Participants will be provided with a cool bag to carry their eye drops around and can keep this bag when they finish the trial.

The possible risks of participating:
1. Possible side effects from taking the new fluid-gel eye drops
2. The treatment may not be effective
3. The participant's DED symptoms may get worse
4. Attending multiple hospital visits to monitor eye health and safety
5. Time taken to complete the tests during the visits
6. Slight discomfort from some of the tests
7. Time taken to complete the questionnaires may be tiring
8. Participants must keep the eye drop cool if they are out for the day, however individual cool bags with ice packs will be supplied to participants for them to use and keep once their involvement in the trial has ended

Where is the study run from?
The trial is run by the University of Birmingham (UK) and will take place in the Birmingham and Midland Eye Centre, City Hospital Birmingham (UK)

When is the study starting and how long is it expected to run for?
December 2022 to December 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) Programme (UK) (Award ID: II-LA-1117-20001)

Who is the main contact?
OPtiCS-OSD Trial Manager, OPtiCS-OSD@trials.bham.ac.uk

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1005852

Central Portfolio Management System (CPMS)
54519

Protocol serial number
RG_18-239

Study information

Scientific Title
Therapeutic fluid-gels for eye disease: Ocular Surface Disease. A phase I/IIa safety trial evaluating allogeneic donor serum gel in patients with severe ocular surface disease (OPtiCS-OSD)

Acronym
OPtiCS-OSD

Study objectives
To assess the safety and tolerability of a new fluid-gel eyedrop alone (called FLG-1001) and containing blood serum (called FLG-SED1) in participants with moderate to severe dry eye disease

To assess the effects of a new fluid-gel eyedrop alone (called FLG-1001) and containing blood serum (called FLG-SED1) on the surface of the eye

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/08/2023, London - Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8057; surreyborders.rec@hra.nhs.uk), ref: 23/LO/0064

Primary study design
Interventional

Study design
Randomized placebo-controlled open-label study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ocular surface disease, dry eye disease

Interventions
For each eye drop of the investigational medicinal product (IMP), one dose is considered to be a single drop to both eyes and, in all stages, participants will continue to use their standard eye treatment as often as required throughout the trial.

In Stage 1, six DED patients will receive each treatment for one day over three consecutive days. On Day 0, one dose of ATF-Allo-SED will be administered in the clinic in the morning, followed by two doses in the clinic in the afternoon, and then four doses administered by the participant at home during the afternoon/evening. On Day 1, FLG-1001 will follow the same dosing pattern as Day 0 first in the clinic and then at home. On Day 2, FLG-SED1 will follow the same dosing pattern as Day 0 and Day 1 in the clinic and then at home. Participants will attend the clinic for a final follow-up visit on Day 3.

In Stage 2, 30 DED patients will be given (at random via an online tool) either FLG-1001, FLG-SED-1 or ATF-Allo-SED (10 participants per trial arm) for a minimum of 6 doses per day for 7 days,

then as frequently as required until Day 42 of treatment, followed by one follow-up visit one week later.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
FLG-1001, FLG-SED1, ATF-Allo-SED

Primary outcome(s)
Safety and tolerability:
1. Occurrence of related serious adverse events (SAEs) measured using study records over the 3-day trial period in Stage 1 and up to Day 49 in Stage 2
2. Worsening of symptoms recorded as adverse events as defined by CTCAE v5.0 and measured using study records over the 3-day trial period in Stage 1 and up to Day 49 in Stage 2

Key secondary outcome(s)
1. Impact on Symptoms and Quality of Life measures comprise:
1.1. Vision-related function, ocular symptoms and environmental triggers measured using the Ocular Surface Disease Index (OSDI) via 12 questions resulting in an overall score between 0-100 at Baseline, Day 0 and Day 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2
1.2. Frequency and severity of ocular dryness measured using the Symptoms Assessment questionnaire in Dry Eye (SANDE) via 2 visual analogue scales measuring from 0 -100mm at Baseline, Days 0, 1, 2 and 3 in Stage 1 and at Baseline and Days 0, 1, 7, 14, 21, 28, 35, 42 and 49 in Stage 2
1.3. Dye eye symptoms and the impact of the condition on daily life measured using the Impact of Dry Eye on Everyday Life (IDEEL) measures via 57 questions organised into 3 modules (dry eye symptom bother, dry eye impact on daily life and dry eye treatment satisfaction) resulting in an overall score between 0-100 at Baseline, Day 0 and Day 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2
1.4. The sensitivity of the other questionnaires measured using a Perceived Changed in Health Questionnaire (PCQ) developed by the trials team comprising 5 questions related to eye symptom changes and 3 questions related to environmental impact changes on Day 3 in Stage 1 and at Days 14, 28, 42 and 49 in Stage 2

2. Visual function measures comprise:
2.1. Visual acuity measured using the LogMAR score on a logMAR visual acuity chart ranging from 1.0 logMAR (low vision) to -0.3 logMAR (good vision) in 0.1 logMAR steps at Baseline, Days 0, 1, 2 and 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2
2.2. Ability to read fixed short sentences and near contrast sensitivity measured using the LogMAR score assessed on an electronic tablet-based functional vision test (Optom Central App) to give a score for reading 14 sentences of decreasing print size between 1.0 and -0.1 logMAR, each consisting of 14 words (Radner reading speed test) at 40 cm of distance at Baseline, Days 0, 1, 2 and 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2

3. Tolerance measures comprise:
3.1. Tear and blink quality measured using the Ocular Surface Analyser (IDRA machine) at Baseline, Days 0, 1, 2 and 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2

3.2. Corneal and conjunctival damage measured using a slit-lamp with SICCA ocular staining score (OSS) at Baseline, Days 0, 1, 2 and 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2
3.3. Corneal epithelium and corneal nerve plexus measured using in vivo-confocal microscopy at Baseline, Days 0, 1, 2 and 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2

4. Tear film measured using image analysis of photographs taken with and without fluorescein and the IDRA machine at Baseline, Days 0, 1, 2 and 3 in Stage 1 and at Baseline and Days 0, 14, 28, 42 and 49 in Stage 2

Completion date
18/12/2027

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. ≥16 years of age
2. Moderate to severe dry eye symptoms (Ocular surface disease index (OSDI) score ≥33)
3. Lubricant requirement ≥ 2 hourly
4. Stable on their current Serum Eye Drop (SED) therapy for >3 months (defined as no need for acute intervention in preceding 3 months) or have previously used SED as part of their ocular therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
For Stages 1 and 2:
1. Unwilling to stop wearing contact lenses for the duration of the trial

2. Active seasonal allergic conjunctivitis (hay fever)
3. Presence of active ophthalmic infection: bacterial, fungal or viral
4. Presence of persistent infective corneal ulcers or current eye condition impacting on the trial as judged by a clinician
5. Known hypersensitivity to any of the components of the trial or procedural medication
6. History of drug, medication or alcohol abuse or addiction
7. Unable to understand, speak and write the English language
8. Vision insufficient to be able to do all the assessments as judged by the participant
9. Use of any investigational agent within 4 weeks of trial entry
10. Participation in another investigational medicinal product (IMP) or ophthalmic interventional clinical trial at the same time as the present trial
11. Participant has received a live attenuated vaccine within 30 days of trial entry
12. Participants on an unstable dose of antidepressants or not willing to stay on the same dose throughout the trial duration
13. Participants on an unstable standard daily dose of inhaled steroids or not willing to stay on the same dose throughout the trial duration PRN may differ but the standard daily dose prescribed must not vary).
14. Participants who are not willing or able to adhere to trial procedures and/or schedule
15. Participants with evidence of significant acute or chronic medical or psychiatric condition that, in the judgement of the investigator, would compromise the participant's safety or ability to complete the trial.
16. Participants who are currently pregnant or breast-feeding
17. A woman of child-bearing potential (WOCBP) who does not agree to use a method of birth control (including barrier methods) during heterosexual intercourse from screening until 1 day after last trial treatment (see notes below)
18. Females of childbearing potential using hormonal contraception for less than 3 months prior to trial entry, or using hormonal contraception and not willing to stay on it for the duration of trial
19. Females taking Hormone Replacement Therapy (HRT) not willing to remain on treatment for the trial duration or have started HRT within the last 3 months prior to trial entry or are on an unstable dose of HRT
20. Male, if not vasectomised, who does not agree to use barrier contraception (condom) during heterosexual intercourse from screening through to 1 day after the last dose of trial treatment.

For Stage 2 only
1. Previous entry into the trial

Date of first enrolment
30/04/2025

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham and Midland Eye Centre (BMEC)
Birmingham City Hospital
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Invention for Innovation Programme

Alternative Name(s)
NIHR Invention for Innovation Programme, i4i

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the CRUK clinical trials unit in accordance with the CRCTU data-sharing

policy: https://www.birmingham.ac.uk/research/crctu/Data-sharing-policy.aspx. Any request to access clinical trial data needs to be requested in writing via the CRCTU data-sharing request form. These data will only be made available after the full analysis of the study data has been undertaken and published in addition to the generation of a complete study report.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			17/11/2026	No	No