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An early-stage study to see if U8:ranibizumab eye drops are safe, well-tolerated, and effective for patients with a specific eye condition called choroidal neovascularisation

Submission date 30/01/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 12/02/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 02/07/2026	**Condition category** Eye Diseases	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
U8:ranibizumab eye drops are being developed as a potential treatment for wet age-related macular degeneration (AMD), which is where abnormal blood vessels grow in the macula (part of the eye), leading to fluid or blood leakage, rapid damage to central vision, and eventual scarring. Symptoms include distorted vision, blind spots, and difficulty seeing colours. The current medicine used to treat wet AMD is given by injection to the eye, which is an uncomfortable and potentially risky procedure for patients. A medicine given as an eye drop would be minimally invasive and would eliminate any side effects caused by the injection procedure. In this trial, we will investigate whether the study drug causes any important side effects and compare its effectiveness with medicines currently used to treat wet AMD.

Who can participate?
Patients aged 60+ years who have been diagnosed with wet AMD

What does the study involve?
Participants will initially receive three doses of the current medicine used to treat wet AMD and then they will be provided the study drug to self-administer once daily for 12 weeks. Participants will be monitored throughout the trial for any side effects and they will return to the unit every 2 weeks for safety assessments to be performed. Once participants have completed dosing, they will be monitored for a further 4 weeks for any side effects. Participants will return to the unit for one final visit at the end of the follow-up period to be discharged from the trial and returned to standard of care treatment. Participants will be involved in the trial for 28 weeks (7 months) in total, from the first injection of the current medicine until the discharge visit.

What are the possible benefits and risks of participating?
Although ranibizumab has been used for many years in eye treatments, it has previously been administered as an injection rather than as an eye drop. The eye drop being tested in this study is therefore new and has not been available before, meaning that only limited information is

currently available about its effects. So far, no side effects have been observed when ranibizumab eye drops have been used in living eyes. Because this particular ranibizumab formulation has not previously been used in humans to treat wet AMD, the data we have are limited. It is unlikely that you will experience all, or even many, of the side effects listed below, but it is not possible to predict which ones you may experience or how severe they might be. Given the limited data, there is also a possibility that other side effects could occur.
Possible side effects associated with ranibizumab eye drops include: eye discomfort or pain, very mild irritation (including slight redness or swelling of the eye), and occasional minor eye discharge.
Side effects that have been linked to chitosan include constipation, flatulence, and abdominal symptoms. Lutrol-127 has been associated with mild eye or skin irritation.
Other potential risks include:
Eye examination (as part of standard care): This may be uncomfortable, as you will need to remain still for 3–4 minutes, and bright or flashing lights may be used, which can cause temporary discomfort.
Routine eye drops used during eye examinations (as part of standard care):
Dilating drops (phenylephrine 2.5%, proxymetacaine hydrochloride 0.5%, and tropicamide 1%) may occasionally cause allergic reactions, breathing difficulties, low blood pressure, palpitations, abnormal heart rhythm (arrhythmia), heart attack, redness or irritation of the eyes, headache, blurred vision, nausea, or dizziness.
Fluorescein sodium 1% eye drops can, in very rare cases, cause allergic reactions, irritation, or swelling of the eye.
Any potential side effects or reactions will be minimised through more frequent follow-up visits every 2 weeks during the trial while participants are using the study eye drops. This regular monitoring will help identify any problems early. These visits are more frequent than those in standard care, which normally occur every 2 months.
Participants will be closely monitored and if there is any concern, then they will be returned to standard care (eye injections).

Where is the study run from?
Imperial College Ophthalmology Research Group Unit (UK), Western Eye Hospital

When is the study starting and how long is it expected to run for?
April 2026 to December 2026

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Prof. Francesca Cordeiro, m.cordeiro@ucl.ac.uk

Contact information

Type(s)
Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1011235

Sponsor's protocol code number
118988

Study information

Scientific Title
A Phase I/IIa open-label proof of concept study to assess the safety, tolerability and efficacy of U8:Ranibizumab Eye drops in patients with choroidal neovascularisation

Acronym
AVID

Study objectives
Primary objective:
To assess the safety and tolerability of topical U8:ranibizumab 8.5 mg/ml eye drops

Secondary objective:
To assess the efficacy of U8:ranibizumab 8.5 mg/ml eye drops

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 26/03/2026, London - Surrey Borders Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; surreyborders.rec@hra.nhs.uk), ref: 26/LO/0164

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Wet age-related macular degeneration

Interventions
U8:ranibizumab 8.5 mg/ml eye drops – a single daily dose for 12 weeks

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Ranibizumab

Primary outcome(s)
Observations relating to local ocular tolerability, including: visual analogue scale (VAS) scores for comfort, slit lamp biomicroscopy findings (e.g., conjunctival hyperaemia, corneal changes), visual acuity and fundus ophthalmoscopy
1. A global ocular discomfort score will be determined using a 100 mm visual analogue scale (VAS) on which 0 means no symptoms and 100 means the worst possible discomfort. This evaluation is to be performed before any ophthalmic assessment at a given study visit
2. Specific ocular symptoms assessed at the time of the VAS including foreign body sensation, burning/stinging, itching, pain, sticky feeling, blurred vision, photophobia
3. Slit-lamp examination to assess the eyelid margin, conjunctiva, cornea, anterior chamber, iris and lens with the instillation of fluorescein to evaluate corneal fluorescein staining (modified Oxford scale) and tear film break-up time

Measured 2 weekly whilst taking the trial eye drop, starting from 1 month (30 days) following the third standard anti-VEGF injection 3 until the patient completes 4 months of the trial eye drop.

Key secondary outcome(s)
Secondary efficacy endpoint and outcome measures:
Patterns of disease activity that may need for retreatment where the re-treatment with intravitreal ranibizumab is indicated by any new or increase in disease activity as determined by:
1. >5-letter decrease in VA compared to previous vision
2. Any evidence of disease activity on SD-OCT (e.g. intraretinal fluid, subretinal fluid, or subretinal pigment epithelial fluid) using Spectralis-OCT

Safety endpoints:
1. Observations on the safety and tolerability of U8:ranibizumab 8.5 mg/ml eye drops, including ocular and non-ocular events noted during treatment and 30 days following trial discontinuation.
2. Non-ocular adverse events will be assessed for the safety set; ocular adverse events will be assessed for the primary treated eye set.
3. Safety will be assessed through AEs, and change in local ocular tolerability - assessed using a visual analogue scale (VAS), slit-lamp biomicroscopy to assess conjunctival hyperaemia and corneal toxicity, visual acuity and fundus ophthalmoscopy
4. A global ocular discomfort score will be determined using a 100 mm visual analogue scale (VAS) on which 0 means no symptoms and 100 means the worst possible discomfort. This evaluation is to be performed before any ophthalmic assessment at a given study visit.
5. Specific ocular symptoms to be assessed with the VAS include: foreign body sensation, burning /stinging, itching, pain, sticky feeling, blurred vision, photophobia
6. Slit-lamp examination to assess the eyelid margin, conjunctiva, cornea, anterior chamber, iris and lens with the instillation of fluorescein to evaluate corneal fluorescein staining (modified Oxford scale) and tear film break-up time.
7. Concomitant medication use will also be documented.
8. All SAEs reported to or noted by the clinician from the time the patient signs the informed consent until 30 days after study discontinuation will be recorded in the AE CRF and reported to Sponsor (please see section 9: Pharmacovigilance). All AEs will be captured on the AE CRF throughout the entire study period. AEs detected through ophthalmic examinations will be collected if available.

Measured 2 weekly whilst taking the trial eye drop, starting from 1 month (30 days) following the third standard anti-VEGF injection 3 until the patient completes 4 months of the trial eye drop

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Aged ≥60 years at the time of signing informed consent.
2. Males and females (WONCBP*)
3. Clear optical media in the studied eye.
4. Refractive error not higher than spherical equivalent of 10 D and best corrected visual acuity equal to 6/24 or better at qualification.

5. Subjects who have capacity to consent, have personally signed and dated the informed consent form
6. Subjects who are having treatment with ranibizumab for wet AMD initiated.
7. Subjects should have shown a good response to loading doses of anti-VEGF (3 injections of anti-VEGF over 3 months) before ranibizumab eye drops are started. The good response will be as determined by the clinician.
8. Ability to administer eye drops independently or with assistance

*WONCBP: not considered to be a women of childbearing potential, i.e., postmenopausal or permanently sterilised (e.g. tubal occlusion, hysterectomy, bilateral salpingectomy). A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. A high follicle-stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single FSH measurement is insufficient.

** Participant will be provided with necessary training tools to facilitate eye drop use, this will be through the means of visual graphics and booklets demonstrating use.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Subjects with “only eye” (one functional eye)
2. Presence of severe, unstable or uncontrolled systemic disease, for example, recent myocardial infarction, recent stroke
3. Body weight <40 kg or >150 kg
4. If patients are unable to self-administer, comply with the study or follow-up procedures, we will explore whether there is a carer or friend/relative who can. If there is no such person who can help instil drops, then this patient will be excluded.
5. Subjects who have had ocular surgery within the past 3 months, or planned surgery in the study eye during the course of the trial
6. Currently being treated for cancer or any other disease likely to adversely affect participation in this study
7. Positive Hepatitis B surface antigen (HBsAg), Hepatitis C virus antibody (HCV Ab) or Human Immunodeficiency Virus (HIV) 1 and 2 antibody results, as per patients’ electronic medical

records
8. History of alcoholism or drug addiction within the last 2 years, as per patients' electronic medical records
9. History or active uveitis
10. History of systemic vasculitis or collagenosis
11. Evidence of previous retinal vascular disease, for example, retinal vein occlusion, retinal artery occlusion
12. Individuals with terminal illness, or clinically significant mental illness as judged by the investigator
13. Simultaneous participation in a study that includes administration of any investigational drug or procedure
14. Systemic or ocular treatment with any VEGF inhibitor other than ranibizumab in the 90 days prior to enrolment
15. The non-study eye has a best corrected visual acuity (BCVA) worse than 20 letters (ETDRS) at the screening visit
16. Women of childbearing potential (WOCBP)
17. If participant is unable to read and understand English language

Date of first enrolment
20/05/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Western Eye Hospital
153-173 Marylebone Road
London
England
NW1 5QH

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available