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Light-Touch Study

Submission date 27/06/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/09/2024	**Overall study status** Ongoing	
Last Edited 24/10/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
The Light Touch study looks at patients with neovascular age-related macular degeneration (nAMD) who have been receiving regular intravitreal injections and would be eligible to switch to a new agent, faricimab. The usual approach to switching would require an initial 4 injections over 4 months. This study looks at whether starting treatment with fewer drug injections (i.e., a "light touch") can still help patients see well, aiming to make treatment less demanding by reducing the number of doctor visits and injections needed.

Who can participate?
Patients aged 50 years or older with nAMD who have been previously treated with anti-angiogenic treatment (excluding faricimab) and undergone an initial induction phase of three monthly injections

What does the study involve?
The study will compare two treatment regimens of faricimab: the standard induction phase (four initial monthly injections) versus a "light touch" regimen (one initial injection followed by personalized treatment intervals). The total study period is 112 weeks, including a 56-week treatment and follow-up phase for participants.

What are the possible benefits and risks of participating?
Faricimab has been widely used globally and the UK for diabetic macular oedema and nAMD and is EMA and MHRA approved for these indications and NICE recommended for nAMD and diabetic macular oedema (DMO). Cumulative safety data to date does not show an increased risk of any ocular or systemic adverse events with this anti-VEGF agent compared to other similar drugs used for these indications. There is therefore no risk to the use of this drug over and above standard care. Optical coherence tomography (OCT) and optical coherence tomography angiography (OCTA) are non-invasive tests that takes images of the inside of the eye. They do not touch the eye, and are painless. There are no known side effects or complications. These are used in standard care so the risks are no greater than standard care.

Where is the study run from?
Moorfields Eye Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2024 to November 2027

Who is funding the study?
Roche Products Limited (UK)

Who is the main contact?
Dun Jack FU, d.fu@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Dun Jack Fu

Contact details
162 City Road
London
United Kingdom
EC1V 2PD
+44 (0)20 02072533411
d.fu@nhs.net

Type(s)
Principal investigator

Contact name
Dr Sobha Sivaprasad

Contact details
162 City Road
London
United Kingdom
EC1V 2PD
+44 (0)20 02072533411
sobha.sivaprasad@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1010355

Protocol serial number
SIVS1069, CPMS 63966

Study information

Scientific Title
A multicentre randomised controlled clinical trial testing the non-inferiority of a lighter to the standard initial dosing regimen of faricimab in patients with pretreated neovascular age-related macular degeneration

Acronym
Light Touch Study

Study objectives
For patients with wet age-related macular degeneration (AMD) that switch to faricimab, it is not known how frequently the injections should be given after switching. This study will determine whether a single treatment (a ‘Light Touch’) at the beginning followed by a personalised treatment interval is as clinically effective as an intensive period of four monthly treatments (an ‘induction phase’) followed by personalised treatment intervals.

The primary objective hypothesises that the intervention “Light Touch” arm will be non-inferior to the standard of care (SoC) "Induction Phase" arm in terms of visual outcome at an average of Week 52 and Week 56.
The secondary objectives of the Light Touch Trial aim to explore additional outcomes beyond comparing change in visual acuity. Specifically, the trial seeks to answer the following questions:
1. Visual acuity improvements: how many patients experience improvements in their vision after switching to faricimab, and how significant are these improvements?
2. Avoiding vision loss: how many patients manage to avoid losing vision during the trial?
3. Vision quality over time: how consistent is the treatment response over time in terms of visual acuity?
4. Eye anatomy changes: what changes occur in the central part of the retina and overall eye anatomy, and how do these changes correlate with treatment?
5. Treatment frequency: how often do patients need injections after switching to faricimab, and can the intervals between treatments be safely extended?
6. Patient experience: what are the patient-reported outcomes regarding their quality of life, burd

Ethics approval required
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Ethics approval(s)
approved 05/09/2024, South Central - Hampshire A Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048135; hampshirea.rec@hra.nhs.uk), ref: 24/SC/0237

Study design
Open single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients with nAMD in at least one eye which were previously treated with anti-angiogenic therapy that would not allow injection interval extension will be randomised 1:1 to either: Standard of Care (“Induction Phase”) Arm or the Intervention (“Light Touch”) Arm.
Standard of Care (“Induction Phase”) Arm: An initial induction (also known as loading) phase, a total of 4 intravitreal injections of faricimab 6 milligrams (mg) once every 4 weeks (Q4W) starting from baseline up to and including Week 12.
Treat-and-extend pathway (T&E) from Week 20 to Week 56 (final study visit).

Intervention (“Light Touch”) Arm: One intravitreal injection of faricimab [6 mg, 0.05 mL solution] at baseline. Duration between baseline and subsequent treatment visit will be the number of weeks in pre-switch treatment interval. T&E starting from the second visit (“Light Touch”) and continuing to Week 56 (final study visit). Pre-switch treatment interval is defined as the duration between injections required by the study eye prior to faricimab switch. This is determined by the principal investigator based on the last 3 treatment visits prior to switch and considering non-clinical factors such as clinic cancellations and patient-factors.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome(s)
Change in best corrected visual acuity (BCVA) from baseline to an average of Week 52 and Week 56, as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at a distance of 4 meters

Key secondary outcome(s))
Measured at Baseline, Week 20 and Week 56:
1. Efficacy on additional BCVA outcomes
2. Efficacy of anatomic outcome measures
3. Frequency of treatment administration
4. Safety outcomes
5. Patient-reported outcomes (PROs), including the visual function questionnaire 25 (VFQ25), EuroQol 5D (EQ5D), attitude towards injection burden

Completion date
30/11/2027

Eligibility

Key inclusion criteria

1. Patients aged 50 years or older
2. Patients must have macular neovascularization secondary to neovascular age-related macular degeneration (nAMD) in the study eye.
3. The study eye must have been previously treated with anti-angiogenic treatment (excluding faricimab) and undergone an initial induction phase of three monthly injections.
4. The study eye could not extend treatment interval beyond 12 weeks due to neovascular exudative activity, which includes intra- or submacular fluid, subretinal hyperreflective material (SHRM), or hemorrhage.
5. Best corrected visual acuity (BCVA) must be at least 24 Early Treatment Diabetic Retinopathy Study (ETDRS) letters.
6. Patients must have the ability and willingness to undertake all scheduled visits and assessments.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Sex
All

Key exclusion criteria
1. Individuals who have not previously received anti-angiogenic treatment.
2. Prior administration of faricimab to the study eye.
3. Presence of fibrosis or atrophy in the central 1 mm of the ETDRS grid, active ocular inflammation, or infection in the study eye.
4. Tractional retinal detachment, preretinal fibrosis, or macular thickening secondary to an epiretinal membrane or vitreomacular traction affecting the macular architecture.
5. Any current or history of ocular disease other than nAMD that may confound assessment of the macula or affect central vision in the study eye.
6. Presence of uncontrolled glaucoma.
7. Any intraocular surgery within 3 months prior to randomization.
8. Females who are pregnant, breastfeeding, or intending to become pregnant during the study period.
9. Systolic blood pressure greater than 180 mmHg or diastolic pressure greater than 100 mmHg at rest.
10. History of stroke or myocardial infarction within the last 6 months.
11. Any disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of the investigational drug or might affect interpretation of the results, or renders the patient at high risk for treatment complications.

Date of first enrolment
10/11/2024

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
Moorfields Eye Hospital

ROR
https://ror.org/03tb37539

Funder(s)

Funder type
Industry

Funder Name
Roche

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date