

A study of photodynamic therapy for long-lasting central serous chorioretinopathy

Submission date 20/12/2025	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/03/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 10/04/2026	Condition category Eye Diseases	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Central serous chorioretinopathy (CSCR) is an eye condition where fluid builds up under the retina, causing blurred or distorted vision. In many cases, the fluid clears up on its own, but in some people it persists for months or years, leading to permanent vision loss. There is currently no proven treatment for chronic CSCR.

Photodynamic therapy (PDT) is a laser treatment that uses a drug called verteporfin to target abnormal areas in the eye. Although PDT is used in some NHS hospitals to treat CSCR, there is limited evidence from clinical trials to show how effective or safe it is.

The PAINT trial will compare PDT using verteporfin with a placebo (dummy) treatment in people with chronic CSCR. The placebo involves the same laser procedure but without the active drug. The study will help determine whether PDT improves vision and reduces fluid under the retina better than placebo.

Who can participate?

Around 140 participants will be recruited from at least 13 hospitals and clinics across the UK. Participants must have visual impairment due to Central Serous Chorioretinopathy (CSCR) of more than 4 months duration.

What does the study involve?

Participants will be randomly assigned to receive either PDT or placebo and followed for 12 months. They will attend clinic visits for eye scans, vision tests, and questionnaires. Some participants may be offered repeat treatment if their condition does not improve. A small blood sample may be collected to explore genetic factors that affect treatment response.

The study is funded by the National Institute for Health and Care Research (NIHR) and managed by the Bristol Trials Centre. It has been designed with input from patients who have experience of CSCR and PDT. Their feedback helped ensure the study is acceptable and practical for participants.

The results will help guide future treatment decisions and may lead to better care for people with chronic CSCR.

What are the possible benefits and risks of participating?

Benefits:

Not provided at time of registration

Risks:

Participation in the PAINT trial may involve some risks and burdens. These are outlined below in plain language, along with steps to minimise them:

Light sensitivity after treatment:

Participants receiving photodynamic therapy (PDT) with verteporfin may become sensitive to light for up to 48 hours. This can cause skin discomfort or sunburn if precautions are not followed. To minimise this risk, participants will be given clear instructions to avoid direct sunlight and bright indoor lighting, wear protective clothing (e.g. long sleeves, sunglasses, hat), and use curtains indoors. A safety bracelet will be provided to alert healthcare professionals in case of emergency.

Temporary blurred vision:

Some participants may experience blurred vision for a few days after treatment. This is expected and usually resolves quickly. Participants will be advised to contact the trial team if their vision worsens or does not improve after four days.

Discomfort from intravenous infusion:

All participants will receive an intravenous infusion (either verteporfin or placebo). This may cause mild discomfort, bruising, or anxiety. Only trained staff will administer the infusion, and participants will be monitored during and after the procedure.

Eye imaging and assessments:

Participants will undergo several eye scans and visual tests (e.g. OCT, FFA, ICGA). These are non-invasive but may be time-consuming and tiring. Visits will be scheduled flexibly, and participants can take breaks during assessments. Optional tests (e.g. microperimetry) will only be performed at sites where available and with participant agreement.

Blood sample for genetic testing (optional):

Participants may be asked to provide a blood sample for future genetic research. This is optional and will not affect participation. Samples will be collected by trained staff, stored securely, and anonymised. No individual results will be returned.

Time commitment and travel:

Participants will attend several clinic visits over 12 months. This may be inconvenient. Travel expenses will be reimbursed, and appointments will be scheduled flexibly. Participants may be offered appointments at alternative sites if needed.

Emotional impact:

Some participants may feel anxious about their diagnosis or treatment. Others may be disappointed if allocated to the placebo group. The trial team will provide clear information and reassurance. All participants will be offered rescue treatment if their vision worsens.

Confidentiality and data security:

Personal and medical data will be collected and stored securely using REDCap. Only authorised staff will have access. Identifiable data will be separated from research data. The risk of data breach is low and mitigated by strict data protection procedures.

Patient and Public Involvement (PPI):

Risks and burdens have been reviewed with patients who have experience of CSCR and PDT. Their feedback helped shape the study design, including flexible visit windows and clear communication materials. They felt the risks were acceptable and the trial was well designed. All risks and burdens are described in the Participant Information Sheet in clear language. The trial team will monitor safety throughout the study and make changes if needed to protect participants.

Where is the study run from?

University of Bristol - Bristol Trials Centre (UK)

When is the study starting and how long is it expected to run for?
January 2026 to February 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
paint-trial@bristol.ac.uk

Contact information

Type(s)

Principal investigator, Scientific, Public

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)
1012257

Central Portfolio Management System (CPMS)
70975

Protocol serial number
RHMOPH0341

Study information

Scientific Title

Photodynamic laser therapy with verteporfin versus Placebo for chronic central serous chorioretinopathy: the Paint RCT

Acronym
PAINT

Study objectives

To evaluate whether best corrected visual acuity following PDT is superior to placebo in eyes with chronic CSCR.

In addition to seeing if vision improves, we also want to answer other important questions. Does the PDT treatment work better than a placebo at getting rid of the fluid that builds up under the retina? Is the treatment safe for patients? Do patients feel their day-to-day vision has improved after receiving the treatment? We will also investigate if the treatment helps people see better in dim light. Finally, we want to see how quickly the fluid disappears and find out if the treatment helps to prevent or cause any long-term changes to the important cell layers at the back of the eye.

Ethics approval required

Ethics approval required

Ethics approval(s)

Not yet submitted

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Treatment

Study type(s)

Efficacy, Safety

Health condition(s) or problem(s) studied

Central Serous Chorioretinopathy (CSCR)

Interventions

This is a multicentre, double masked, placebo controlled randomised trial comparing half dose photodynamic therapy (PDT) using verteporfin with placebo infusion plus laser in adults with chronic central serous chorioretinopathy.

Arm 1: Photodynamic Therapy (PDT)

Participants receive verteporfin at 3 mg/m² body surface area, reconstituted and infused intravenously over 10 minutes. Fifteen minutes after infusion starts, PDT laser is applied using a 689 nm non thermal diode laser, at 50 J/cm² fluence for 83 seconds via a contact PDT lens. The treatment area is determined using indocyanine green angiography (ICGA) and corresponds to areas of hypercyanescence associated with subretinal fluid on OCT. PDT is administered at baseline, with re treatment at 4 and/or 8 months if subfoveal SRF ≥50 microns persists or recurs. Rescue PDT is permitted for ≥10 ETDRS letter loss with persistent or recurrent SRF.

Arm 2: Placebo (Dextrose infusion + laser)

Participants receive 15 mL of 50 mg/mL (5%) dextrose solution infused intravenously over 10 minutes, matching verteporfin infusion timing and masking. Fifteen minutes after infusion starts, the same laser procedure is performed with identical parameters, but without verteporfin. Re treatment at 4 and/or 8 months follows the same criteria, and rescue PDT is allowed under identical conditions.

Route and duration: All treatments are given by intravenous infusion followed by laser activation. Total participant involvement is 12 months.

Randomisation: Participants are randomised 1:1 using a secure web based minimisation system (Sealed Envelope Ltd), stratified by site and baseline BCVA (<68 vs ≥68 ETDRS letters). Masking is maintained for participants, clinical assessors, and outcome evaluators.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Visudyne [Verteporfin]

Primary outcome(s)

1. Best corrected visual acuity (BCVA) measured using ETDRS letter score at baseline, 4 months, 8 months, and 12 months, with the primary endpoint at 12 months

Key secondary outcome(s)

1. Subfoveal subretinal fluid (SRF) thickness measured using optical coherence tomography (OCT) at baseline, 4, 8, and 12 months, with the primary comparison at 12 months

2. Systemic and ocular adverse events measured using standard clinical safety assessment methods at continuously throughout the 12 month follow up

3. Atrophy of the retinal pigment epithelium (RPE) defined as hypo autofluorescence ≥50 microns measured using fundus autofluorescence (FAF) at baseline and 12 months

4. Choroidal thickness measured using enhanced depth imaging OCT at baseline and 12 months

5. Time to resolution of SRF and proportion of eyes with persistent SRF measured using OCT at each follow up visit (4, 8, 12 months)

6. Development of choroidal neovascularisation measured using FFA, ICGA, and OCT A at baseline and 12 months (and at re treatment visits if applicable)

7. Low luminance visual acuity (LLVA) measured using ETDRS letters at baseline, 4, 8, and 12 months

8. Patient reported visual function measured using the VFQ 25 questionnaire at baseline and 12 months

9. Mean retinal sensitivity measured using Maia microperimetry at baseline and 12 months (optional, dependent on site capability)

10. Correlation of structural retinal/choroidal biomarkers with functional outcomes measured using multimodal imaging (OCT, OCT A, ICGA, FFA, FAF) at each imaging visit

Completion date

01/02/2029

Eligibility

Key inclusion criteria

1. Participants must be aged 18 years or above.
2. Must have visual impairment due to Central Serous Chorioretinopathy (CSCR) of more than 4 months duration. This is defined by the subfoveal presence of subretinal fluid (SRF) on Optical Coherence Tomography (OCT) with a vertical thickness of at least 50 microns, along with the characteristic appearance of CSCR on Fundus Fluorescein Angiography (FFA) and Indocyanine Green Angiography (ICGA).
3. The study eye must have a best recorded visual acuity (BRVA) score of less than 70 ETDRS letters (equivalent to 6/12 Snellen).
4. The study eye must have clear ocular media and adequate pupillary dilatation to permit photography.
5. Participants must be able to provide written informed consent.
6. Women of childbearing potential must have a negative pregnancy test and be willing to use effective contraception. Women who are post-menopausal for over 12 months or are surgically sterile are also eligible.

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

120 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

General Exclusions:

1. Known hypersensitivity to verteporfin, iodine, sodium iodide, fluorescein, or indocyanine green.
2. Diagnosis of porphyria or a history of severe hepatic impairment (Child-Pugh score >6).

3. Currently breastfeeding.
4. Severe or end-stage renal impairment, defined as an estimated glomerular filtration rate (eGFR) of less than 15.
5. Current use of other photosensitising medicinal products, such as tetracyclines, sulphonamides, phenothiazines, and thiazide diuretics.
6. Use of any oral medication for the specific purpose of treating CSCR (e.g., eplerenone, spironolactone, rifampicin) within the last 6 months.
7. Use of oral corticosteroids within the last 3 months.
8. Participation in another clinical trial involving an Investigational Medicinal Product (IMP) within the last 30 days.

Exclusions Specific to the Study Eye:

1. Evidence of choroidal neovascularization as seen on FFA, ICGA, or OCT-A.
2. Presence of subfoveal retinal pigment epithelial atrophy.
3. Any previous treatment with photodynamic therapy (PDT).
4. Receipt of any anti-VEGF therapy or previous thermal or micropulse laser therapy for CSCR within the last 6 months.
5. Presence of any other ocular disease which could be a cause of retinal or subretinal fluid accumulation, such as diabetic retinopathy.
6. Myopia greater than -6 dioptres.

Date of first enrolment

01/01/2026

Date of final enrolment

30/09/2027

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Study participating centre

Belfast Health and Social Care Trust

Trust Headquarters

A Floor - Belfast City Hospital

Lisburn Road

Belfast

England

BT9 7AB

Study participating centre

Royal Blackburn Teaching Hospital
Haslingden Rd
Blackburn
England
BB2 3HH

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Colchester Dist General Hospital
Turner Road
Colchester
England
CO4 5JL

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
England
GU16 7UJ

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
England
GL53 7AN

Study participating centre
Kings College Hospital
Mapother House

De Crespigny Park
Denmark Hill
London
England
SE5 8AB

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
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L7 8XP

Study participating centre
The Retina Clinic
140 Harley Street
London
England
W1G 7LB

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
162 City Road
London
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EC1V 2PD

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington

Oxford
England
OX3 9DU

Study participating centre

York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
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YO31 8HE

Sponsor information

Organisation

University of Bristol - Bristol Trials Centre

Funder(s)

Funder type

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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 and/or analysed during this study will be stored in a non public repository. Final anonymised datasets will be held in the University of Southampton's designated secure research data repository. Data will be available to bona fide researchers upon request and subject to a data access agreement to ensure compliance with ethical approvals, participant consent, and data protection legislation.

The data available will include anonymised clinical data, imaging derived measurements, and questionnaire data. Data will become available after publication of the main results and will remain accessible for a minimum of 10 years, in accordance with institutional data retention policies. Access will be granted for scientifically valid analyses aligned with the study's objectives, via secure transfer mechanisms. All shared data will be fully anonymised, and participant consent permits anonymised data sharing under controlled access conditions.

IPD sharing plan summary

Stored in non-publicly available repository