

The investigation of eye tear film proteins to see if there is an association with the stage of an eye condition called Retinopathy of Prematurity (ROP) which can occur in some premature babies; and the investigation of eye nerve development in these babies

Submission date 07/10/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/10/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/11/2025	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Retinopathy of Prematurity (ROP) is an eye condition that can cause blindness in premature babies. It happens when the blood vessels in the back of the eye (the retina) don't grow properly after birth. In some cases, they grow in a chaotic way and cause scarring, which can lead to permanent vision loss. In high-income countries, babies at risk are regularly screened and treated, but in lower-income countries, this isn't always possible, and many children lose their sight.

This study aims to find better ways to predict which babies are at risk of developing serious ROP. Researchers will look at proteins found in babies' tears and measure how their eyes respond to light. By comparing these results with standard eye exams, they hope to discover new, less invasive ways to detect and treat ROP early.

Who can participate?

Babies born very early (before 28 weeks of pregnancy) or with a very low birth weight (under 1051 grams) may be eligible to take part in the study. There are some medical reasons why certain babies might not be included.

What does the study involve?

Researchers will collect small samples of tears from participating babies to look for specific proteins linked to ROP. They will also use a gentle test called an electroretinogram (ERG), which measures how the retina responds to light. This is done using soft electrodes placed around the baby's eye while they are in their incubator. The study will also collect basic medical information like age, gender, ethnicity, and oxygen use.

What are the possible benefits and risks of participating?

There is no direct benefit to the babies taking part, but the study could help improve how ROP is detected and treated in the future. The procedures used are safe and non-invasive, and the team will take great care to ensure the babies are comfortable throughout.

Where is the study run from?

The study is led by NHS Greater Glasgow and Clyde, with support from NHS Lanarkshire, Manchester University NHS Foundation Trust, and Birmingham Women's NHS Foundation Trust (UK).

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

February 2025 to September 2027

Who is funding the study?

Fight for Sight (UK)

Who is the main contact?

Dr Anne Cees Houtman, annecees.houtman2@nhs.scot

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)

346891

Protocol serial number

Sponsor Reference: GN23OP457P

Central Portfolio Management System (CPMS)

70694

Study information

Scientific Title

Tear proteomics and electrophysiology in infants at risk of retinopathy of prematurity - TEARDROPS (TEAr pRoteomics Deduce ROP Stage)

Acronym

TEARDROPS

Study objectives

Principle Objective: To identify proteins in the tears of premature babies which can predict ROP requiring treatment

Secondary Research Objectives:

1. To identify a key age window where changes in tear proteins predict the onset of treatment warranted ROP (stage 1)
2. To test the diagnostic accuracy of a single (or paired) tear sample collected in that key age window from a second group of babies (stage 2)
3. To establish whether the electroretinogram (ERG) is feasible and/or useful as a potential predictor of ROP
4. To use the protein analysis to enhance understanding of ROP pathophysiology

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 09/07/2025, South Central - Oxford C Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048271; oxfordc.rec@hra.nhs.uk), ref: 25/SC/0158

Study design

Observational longitudinal prospective multi-centre study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Retinopathy of prematurity

Interventions

In phase 1: tear samples will be collected from premature babies +/- 24 hours of ROP screening. Samples will be collected from both eyes at every screening and stopped when screening completes. Tear samples will be collected via schirmer strips under the eyelid for a maximum of five minutes. In phase 2: the sample collection method is the same. However, babies will only have 1 or 2 samples taken from each eye over a predefined gestational age following data analysis from phase 1. No speculum is used for sample collection. No topical medication is used for sample collection.

Intervention Type

Other

Primary outcome(s)

1. A large tear proteomic dataset from a cohort of over 110 premature infants at very high risk of ROP. Data will be collected via patient notes at each tear sample collection. Tear sample collection will happen +/- 24 hours of planned ROP screening. Tear samples will be collected using a Schirmer strip for a maximum of 5 minutes, or until 5mm of strip wetting has been achieved. Tear strips will be placed under the eyelid of the participant. No anaesthetic or speculum will be used. Tear strips will then be placed into an Eppendorf container containing SDT buffer. Eppendorf containers will then be stored at (-20 degree Celsius) until sent for mass spectrometry testing. Consultant Ophthalmologists will record the ROP findings at each screening. ROP findings will be recorded as per standard international guidelines.
2. Correlations of ROP clinical findings with tear proteomic changes. Tear samples will be analysed at the end of phase 1 of the study via mass spectrometry at a University of Glasgow laboratory. All samples will be transferred to the lab at the end of phase 1. Given samples will have been collected over varying gestational ages, we will review tear mass spectrometry results to see if there is a peak in any particular molecules. We will use data analysis from phase 1 to guide the gestational age of sample collection in phase 2 of the study. Tear samples will be collected in the same way. Alongside this, we will review ROP fundus screening findings.

Key secondary outcome(s)

1. Possible identification of a tear proteomic biomarker, with a critical age window, for treatment-warranted ROP. As above.

Completion date

12/09/2027

Eligibility

Key inclusion criteria

Infants meeting G-ROP criteria (gestational age <28 weeks OR birth weight <1051g). These criteria, stricter than the UK ROP-screening guidelines (gestational age <31 weeks, birth weight <1051g) increase the likely proportion of infants developing treatment-warranted ROP to 50%.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

0 weeks

Upper age limit

28 weeks

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Chronic infectious/ inflammatory conjunctivitis
2. Hydrocephalus (a ventricular index on cranial ultrasound 4mm above the 97th centile for gestational age - Leaven Index)
3. Congenital bilateral ocular anomaly

Date of first enrolment

14/10/2025

Date of final enrolment

12/09/2027

Locations**Countries of recruitment**

United Kingdom

England

Scotland

Study participating centre

Royal Hospital for Sick Children (Glasgow) (3 sites in NHS GGC)

1345 Govan Road

Glasgow

Scotland

G51 4TF

Study participating centre

University Hospital Wishaw

50 Netherton Street

Wishaw

Scotland

ML2 0DP

Study participating centre

Saint Mary's Hospital - (Manchester University NHS Foundation Trust (MFT) - 3 sites)

Oxford Road

Manchester

Scotland

ML2 0DP

Study participating centre

Birmingham's Women Hospital (Birmingham Women's NHS Foundation Trust) (+ peripheral sites within Trust)

Mindelsohn Way

Birmingham

England

B15 2TG

Sponsor information

Organisation

NHS Greater Glasgow and Clyde

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Charity

Funder Name

Fight for Sight

Alternative Name(s)

Fight for Sight, Inc., National Council to Combat Blindness, Fight for Sight (U.S.), FFS

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available on request from Chief Investigator Dr Anne Cees Houtman (annecees.houtman2@nhs.scot)

IPD sharing plan summary

Available on request