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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** Not yet recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 07/10/2025	**Overall study status** Ongoing	
Last Edited 07/10/2025	**Condition category** Neonatal Diseases	

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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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
346891

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor Reference: GN23OP457P

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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 schrimer 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 measure
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 Schrimer strip for a maximum or 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.

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

Overall study start date
01/02/2025

Completion date
01/09/2027

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

Age group
Neonate

Lower age limit
0 Weeks

Upper age limit
28 Weeks

Sex
Both

Target number of participants
58 + 52 = 110

Key exclusion criteria
1. Chronic infectious/ inflammatory conjunctivitis
2. Hydrocephalus (a ventricular index on cranial ultrasound 4mm above the 97th gentile 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
England

Scotland

United Kingdom

Study participating centre
Royal Hospital for Sick Children (Glasgow) (3 sites in NHS GGC)
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
University Hospital Wishaw
50 Netherton Street
Wishaw

United Kingdom
ML2 0DP

Study participating centre
Saint Mary's Hospital - (Manchester University NHS Foundation Trust (MFT) - 3 sites)
Oxford Road
Manchester
United Kingdom
ML2 0DP

Study participating centre
Birmingham's Women Hospital (Birmingham Women's NHS Foundation Trust) (+ peripheral sites within Trust)
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
Research & Innovation
Gartnavel Royal Hospital
1053 Great Western Road
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Scotland
United Kingdom
G12 0YN
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adam.wade@nhs.scot

Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/01/2028

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