TEARDROPS STUDY –PATIENT INFORMATION SHEET phase 1

TEARDROPS is short for Tear Proteomics Determine ROP Stage

We would like to invite you and your baby to take part in our study.

What is the study about and what are its aims?

We know babies born early are at risk of developing an eye condition called retinopathy of prematurity (we'll call this ROP for short from now on). ROP affect the normal development of blood vessels of the retina (the light-sensitive inner lining of the eye) and can lead to sight loss if it is not identified and treated, in time. All babies that were born before 32 weeks and/or weighed less than 1500g at birth will have their eyes checked by an eye doctor (an ophthalmologist), every one or two weeks to see whether ROP has started to develop. The eye doctor's team may also take photographs of the back of your baby's eye. This is called "ROP screening". There is more information about ROP at the end of this sheet.

We are investigating whether a premature baby's normal tear fluid can tell us as much about ROP as the eye doctor's examination. We are calling the tear fluid "tears", but this is not because the babies are crying, it is just the normal fluid around their eyes. We hope that the information in the baby's tears could be used in the future to develop an easier ROP screening process.

In addition to collecting the tear samples, we are recording the tiny electrical signals made by the retina using a non-invasive test called an electroretinogram, or ERG for short. We hope this will help us understand how ROP affects the way the retina works.

Who has been invited to participate and why?

For our results to be helpful for other prematurely-born infants, we need to study babies who were born very early or with very low birthweight. We are therefore studying babies who are born 'extremely' prematurely (before 28 weeks) and/or who had low weight at birth (less than 1051g).

Your baby is suitable because they were born that early and/or with low birthweight. If you are interested, please speak to the clinical team looking after your baby or use the contacts at the end of the sheet. We can discuss the study with you, answer your questions and give you as long as you need to consider participating. If you do want to participate, we will ask you to sign a consent form.

You and your baby do not have to take part. Even if you do agree to take part and sign a consent form, you can withdraw your baby from the study at any point by speaking with your baby's care team. You will not have to give any reason for withdrawing and it will not affect the care your baby receives.

What does participation involve for my baby?

If you consent for your baby to take part, we will take a sample of your baby's tear film on the same day as the eye doctor does their ROP screening examination. This may happen every week or every two weeks, depending on the care your baby needs. To take the sample, a researcher will gently place a small strip of special paper, called a Schirmer strip, under your baby's eyelids. This paper slowly absorbs a very small amount of tear film (much less than a millilitre), which takes up to five minutes. We have used the technique before and babies do not appear to find this unpleasant or uncomfortable. The paper strips are then gently removed and sent to a laboratory for analysis. Analysis usually destroys the sample; if not the sample will be destroyed once the study is completed.

A member of the nursing team will be looking after your baby throughout and you are very welcome to also be there.

We will also collect some clinical and demographic information about your baby (e.g. birthweight, ethnicity, oxygen requirements, weight gain). This information helps us to better understand the variation in ROP severity.

The data collected in the study will be 'pseudonymised'. Pseudonymised means there will be an identifiable record of your baby's details when you enrol into the study. This record will be stored securely within the hospital grounds. Your baby is allocated a study ID when enrolling, and all future documents will be labelled with this ID, and no personal data. What this means is that the ID can be traced back to your baby if needed by the lead researcher. Everything will be kept under a unique 'study ID' number - not under your baby's name and with personal data removed. Only the principal investigator could retrieve your baby's details should it be necessary to go back to clinical data, e.g. if research data was not properly recorded, or lost, following the ROP-screening. Only data which may be helpful to understand ROP will be collected. We will also use the retinal photographs taken routinely as part of ROP screening, to record any ROP progression.

How long will participation last?

Once your baby has grown old enough to no longer need ROP screening, or has completed any ROP treatment they may need, we will stop collecting tear samples when their ROP screening examinations also stop.

When, where, and how many times will each study activity be carried out?

We will take tear samples on the same day as the eye doctor does your baby's ROP screening examination. This may happen every week or every two weeks, depending on the care your baby needs. All tear samples will be collected on the neonatal unit where your baby receives their routine care: the only exception to this would be if your baby is discharged home but still has to come back to the hospital for their ROP screening. The number of times tear samples are taken will depend on each baby's age and ROP screening result, but may be as few as once or, for a few babies, as many as about ten. Usually ROP screening finishes when babies reach their due date.

We will also record the ERG just before the ROP screening itself, if you have also agreed for your baby to have this test. We will keep your baby in the dark for about ten minutes before and during the test using a special light-proof drape and eye mask. The eye is gently held open with an ophthalmic instrument, the same one as will be used for the ROP screening. Only one eye will have an ERG. Three small sensors are placed close to the baby's eye and a handheld device shines a series of blue and then red flashes of light. The device records the tiny electrical responses made by your baby's retina in response to these flashes. ERGs will only be recorded on babies who are still on the neonatal unit.

What happens to tear samples already taken if I withdraw?

If you withdraw, we will take no further tear samples. We will keep any tear samples we have already collected and continue to analyse these as planned. We may have already analysed your baby's earlier tear sample(s) by the time you withdraw.

Potential risks and benefits of participation

The paper strips collecting the tears may cause mild discomfort, although we have not seen this so far when using them. Any handling of premature babies can cause distress, and as for all procedures, nursing support will be in place to keep babies as settled as possible. In the unlikely event that tear sampling cause your baby distress or to become unstable, they can be paused and resumed later once the baby is settled again.

There is no direct benefit to your baby from taking part. The results from their participation may only benefit future prematurely-born infants.

Contact details

If you would like more information or to discuss the information provided, please contact:

Dr Anne Cees Houtman, Consultant Ophthalmologist

Chief Investigator, TEARDROPS Study

Email: annecees.houtman2@nhs.scot

Dr Megan Quinn, Ophthalmology Registrar

MD Student – University of Glasgow – TEARDROPS Study

Email – megan.quinn2@nhs.scot

Research Midwives on 0141 232 7600

Email – ggc.obstetric.gcrf@nhs.scot

If you have any complaints or concerns about this research study, please contact:

PASS

The NHS in Scotland has in place arrangements to provide a Patient Advice and Support Service (PASS) for all NHS users. The service is free, confidential, independent of NHSGGC, and fully impartial.

Helpline telephone number: 0800 917 2127

For more information about this service and to find your local bureau, including contact details: https://pass-scotland.org.uk

If you take part and want to contact the team for the duration of participation, please contact:

Dr Anne Cees Houtman, Consultant Ophthalmologist

Chief Investigator, TEARDROPS Study

Email: annecees.houtman2@nhs.scot

Supporting Information

What is ROP?

ROP stands for retinopathy of prematurity. It is the name of the eye condition which some prematurely-born babies get, and it affects the retina, which is the thin layer of nerve cells inside the back of the eye which turns light into tiny electrical impulses and sends these to the brain in the process we call sight. The retina contains lots of intricate nerve cells and also lots of blood vessels which nourish these nerve cells.

When babies are born prematurely, their retinas have not yet fully developed. That includes the nerve cells and the blood vessels. As the prematurely born baby grows, sometimes the retina's blood vessels start to develop abnormally. This means they first stop growing as much as they should, and then 'bounce back' by growing too many and not as well organised as they should be. Usually, this blood vessel problem gets better on its own, but sometimes the condition needs to be treated with drugs or sometimes surgery to correct the problem, to prevent blindness.

This QR code takes you to a good website which describes more about ROP and its treatment.

American Academy of Ophthalmology website with patient information about ROP, https://www.aao.org/eye-health/diseases/what-is-retinopathy-prematurity

More data information

The research team for this study includes four different NHS sites plus two UK universities. Sharing your baby's data (that is, the results of their tear analysis along with their clinical and demographic data) with other researchers is important to ensure that research is open to peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making. At each site, your baby's information will be kept secure by holding direct identifiers separately from health information (only a study ID kept locally will enable linking these). In the longer term, direct identifiers will be destroyed and only fully anonymised data will be kept. Currently, we have no plans to ask for further ethics committee approval for any re-use of the data. We intend to publish our findings in the medical literature and are happy to provide copies, or summaries, to any participant on request (please use contact details here to request this). Individual babies will not be identifiable from any report or publication in the public domain.

Who is organising and funding this study?

This study is sponsored by NHS Greater Glasgow & Clyde and is funded by the charity Fight for Sight (www.fightforsight.org.uk). No-one involved in the study receives any payment of any kind for including your baby in this study.

How have patients and the public been involved in this study?

Parents whose babies took part in an earlier, shorter version of this type of study were asked for their opinions about tear sampling and all were favourable, agreeing that their babies were not bothered by the tear sampling process. This Patient Information Sheet was also reviewed by a parent group whose babies had been cared for at the Royal Hospital for Children's neonatal unit in Glasgow.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by NHS Health Research Authority, South Central – Oxford C Research Ethics Committee.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to your study doctor Dr Megan Quinn, Ophthalmology Speciality Trainee Doctor, megan.quinn2@nhs.scot who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Chief Investigator, Dr Anne Cees Houtman, at annecees.houtman2@nhs.scot.

We do not anticipate that anything will go wrong. In the event that something does go wrong, there are no special compensation arrangements. If you are harmed due to someone's negligence, or your participation in the study you may have grounds for legal action for compensation against the sponsor (Greater Glasgow and Clyde Health Board/University of Glasgow) and/or the University of Glasgow, but you may have to pay your legal costs.

The normal National Health Service complaints mechanisms are available if you wish to complain or have any concerns (Tel: 0141 201 4500, Email: complaints@ggc.scot.nhs.uk).

What rights do I have over my data?

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients or by contacting Dr Anne Cees Houtman, annecees.houtman2@nhs.scot.

Personal data will be collected and stored in compliance with the Data Protection Act 2018 and GDPR.

What are my choices about how my information is used?

- You can stop your baby being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to remove, change or delete data we hold about your baby for the purposes of the study. We might not always be able to do this if it means we cannot use your baby's data to do the research. If so, we will tell you why we cannot do this.