Confidentiality

All information collected during this study will be confidential and only the research team will have access to it. Confidentiality will only be broken if there are health, safety or medical concerns, where referral to an appropriate specialist is required, and has been discussed with you in advance. The data may also be used to form the basis of a bigger trial in the future so your baby's personal data will be stored between 12 months and 3 years with your permission (should you wish to participate).

All paper information (like signed consent forms) will be locked in a filing cabinet in the research office. Personal identifiable data will be stored separately to the research data. Any electronic data will be stored on computers or laptops that are secure with password protection.
The people analysing the results from the study will not have any personal contact details which would be able to identify your child's involvement.
At the end of the study personal data required by administration will only be stored and accessed for up to a year. The research data will be stored for 15 years or in accordance with GOSH Trust policy. It will also be stored in the secure University College London safe haven database and anonymized data (from which you and your baby cannot be identified) will be sent to King's College Trials Unit for analysis.

We, as a research team, will need to use information about your baby from our assessment and the medical records for this research project.
This information will include your child's name, NHS number, and contact details. This information will be used to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

We need to manage your records in specific ways for the research to be reliable so we won't be able to let you see or change the data we hold.

You will need to sign a consent form which will be collected and retained as part of the research process. This is non-anonymised but is kept separate from the research data.

Who should I ask if I have any further questions or concerns?

Please contact the research team at GOSH or UCLH.

Principal Investigator:
Richard Bowman, Consultant Ophthalmologist, Great Ormond Street Hospital, Great Ormond Street, London, WC1N 3JH
Email: richard.bowman@gosh.nhs.uk
Telephone Number: 07847921223

Research Optometrist:
Raimonda Bullaj, 235 Euston Road, Elizabeth Garrett Anderson Wing London NW1 2BU
Email: raimonda.bullaj@gosh.nhs.uk
Telephone Number: 07761054397

If you feel that your concerns have not been addressed or dealt with appropriately or you would like to talk to an impartial team, you can contact the Patient Advise and Liaison Service (PALs) at GOSH who can address your concerns further:

Email: pals@gosh.nhs.uk
Telephone Number: 0207 829 7862

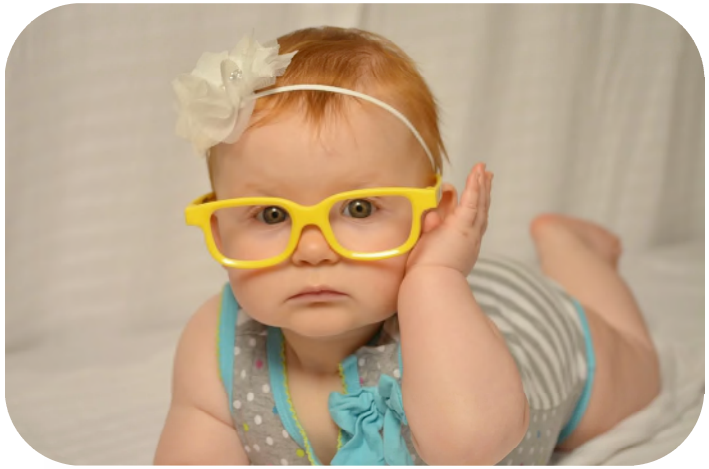
You can find out more about how we use your information at:
www.hra.nhs.uk/information-about-patients/

Everyone who takes part in the study will receive a final report of the findings. This will be sent to you via secure email or through the post.

Parents/Guardians will be reimbursed travel costs for extra travel requirements arising from participation (the visits will not require any over-night stay).

NHS
Great Ormond Street Hospital for Children
NHS Foundation Trust

Can Wearing Near Vision Glasses Help to Improve The Visual Outcome In Babies At Risk Of Brain Injury?



NHS
University College London Hospitals
NHS Foundation Trust

This study is being led by a team at GOSH and UCLH together with other experts in infant vision development from across the UK.

The study will be sponsored by GOSH.
The study has received full funding from the National Institute of Health Research.

The study has been approved by the South-Central Oxford C Research Ethics Committee. There is a separate committee supervising the research as we go along which includes parents of children with and without CVI.

Introduction

The leading cause of sight impairment in children in the UK is **Cerebral Visual Impairment (CVI).** CVI is where parts of the brain responsible for processing vision are not working well, and can be common in children who have had complications around the time of birth (such as those treated with brain cooling) and premature births. Babies use their sight to learn to walk, talk, think and communicate so if we can improve vision early on we may be able to help these babies' general development. As part of this study we would be measuring your baby's vision in different ways including brain responses to visual stimulations to see if there are any visual processing issues.

We plan to trial giving near vision glasses to young (2 and 4 month) babies whom we know to be at risk of CVI (prematurity of <29 weeks gestation or loss of oxygen to the brain around the time of birth known as Hypoxic Ischaemic Encephalopathy or HIE). This is a feasibility study which means we are looking at a small sample of cases to gauge whether parents are willing to try glasses for their babies at a very young age and to analyse the effectiveness.

If you agree to take part, we will be observing your baby's vision more closely than we would normally do. You would be free to withdraw at any stage without affecting your normal clinical care. We would ask that all the data collected up to that point can still be used.

If you decide not to participate, this will not affect any other aspects of your medical care at UCLH or elsewhere.

Study Design

We plan to monitor babies by measuring their vision in different ways including broadband Near Infrared Spectroscopy (fBNIRS); for this, babies will be sat on a parent or carers' lap facing a computer screen whilst we gently shine a light into their eyes. The fBNIRS will be performed before discharge in the neonatal unit and repeated at the follow up appointments. You can opt out of this assessment if you wish.

The other tests we plan to carry out are how your baby responds to a human face, their eye muscle control, if they can follow a small toy in different directions and measurements of their distance & near vision prescription (using a light and an automated instrument). We will also check the health of your babies eyes using dilating eye drops. The drops may sting for a second or two and can cause temporary flushing which soon wears off. These eye drops are quite safe and are very commonly used in tiny babies.

We will look to see if by giving them the near vision glasses, we can improve their vision when we measure it 3 and 6 months (+/- 3 weeks) later and if we can also aid other areas of development.

Previous research has shown improved vision and focusing ability with near vision glasses in older children with CVI, but it has not been evaluated in babies. Babies look at their hands, toys and parents' faces in close up and this is crucial for their development. Many children with CVI lack the ability to focus on things to develop their vision. Near vision glasses will bring their world into focus and also make everything bigger at this vital stage of their development.

We have been giving glasses to small babies for a long time and so we have specially designed frames which are safe and fit well.

IRAS #265584, Version 5, 16.10.2020

Baseline & Follow Ups

In order to see if this idea works, the study will have a 'control group' who will not receive glasses. The decision as to whether your child will receive glasses or not will be determined by chance. If we find out that your child is very long or short sighted, we would refer to the specialist clinic for consideration of prescribing glasses and the chance element would be removed. All babies will receive a full sight test at each visit whether they have received glasses or not.

If the glasses were to cause any harm to the development of your child's vision (we anticipate that harm would be very unlikely) the examinations at 3 and 6 months (+/- 3 weeks) would indicate this, and we would stop the glasses in this case.

If your baby is randomised to get glasses, then you will be given a spectacle prescription. You will need to take this to Great Ormond Street Hospital Eye Department dispensing optician to get the special glasses ordered for your child and then these will be sent out to you when they are ready. There will be further follow up visits involving full eye and vision examination, lasting about 30 minutes, at 3 months and 6 months (+/- 3 weeks) after the initial assessment. These will be roughly at the same time as the normal neurodevelopmental assessments that your child would have as part of their NHS follow up.

FUNDED BY
NIHR | National Institute for Health Research