

Surgical drainage, irrigation and fibrinolytic therapy (DRIFT) in premature infants with post-haemorrhagic ventricular dilatation: Brain function and structure at school age

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Why have I been given this leaflet?

Your baby participated in the DRIFT (Drainage, irrigation and fibrinolytic therapy) Clinical Trial between 2003 and 2006. As part of the DRIFT trial your baby had a full assessment of their development at 2 years.

We are now planning further follow-up of the children in the DRIFT trial at school age, when much more detailed assessment of vision and learning/reasoning skills (cognitive function) is possible. We are interested in how the brain repairs and adapts after suffering a bleed. This will be studied by doing a further brain MRI scan and comparing these images with the original scan performed as a baby. We are also interested to learn about each child's strengths and difficulties and what levels of support the children have required from their parents/carers, as well as from health, community and education services.

Because your baby participated in the DRIFT trial your child has the opportunity to be in the follow-on study.

We performed a pilot study to check which assessments would be acceptable to children of different abilities and their parents. All the assessments were found to be well tolerated and enjoyable for the children involved.

What are the different assessments that will be performed for the study?

A: Cognitive assessment: (45 minutes)

The assessment is the British Ability Scales (BAS III) which consists of 21 short measures of particular types of knowledge, thinking and/or skills. Examples: spotting similarities in pictures, identifying similarities in words, recognising pictures and remembering and recalling objects. This assessment is suitable for children with a wide range of abilities and is very adaptable to children with disabilities or learning difficulties. Where children have very limited abilities the Bayley Scales of Infant and Toddler Development will be used, this was the assessment used at the 2 year follow-up. The tasks will start at a very basic level to enable us to find the ability range for each child. The full assessment will take around 45 minutes and may be paused for rests or refreshments.

B: Visual assessment: (45 minutes)

We will check how well the children can see and how well they can interpret what they see. We will use simple tests that we use every day at the Eye Hospital.

We will test visual acuity (how small an object can be seen) using standard letter or picture charts, with both eyes open and wearing the child's own glasses if they have any. If children find these tests difficult we will see whether they can look at and follow a coloured, or lit, or noisy toy. We will test contrast sensitivity (how well the child can tell the difference between different shades of grey) using standard pictures. We will carefully look at their eye movements as they follow a moving target. We will see how well they can see in the periphery of their vision (how far to the sides, or above or below their line of sight they can spot an object, whilst looking straight ahead). We will test "3D" vision using pictures in books and we will use some games to see how well the children can interpret what they

see (pretending to post a letter, matching some shapes, looking at a moving image, recognizing what objects are in photographs).

We need to know if the backs of each child's eyes are healthy. If they have had an examination with eye drops within the last year, we will get those results from the children's hospital notes. If they have not had an examination with eye drops within the last year we will check their eyes. First we will give some anaesthetic eye drops that just feel like water to make the eyes comfortable and numb. Then we will give some dilating drops to make the pupils become large. After 20 minutes we will look at the back of the eye and measure whether there is any long- or short- sight. If glasses are needed we can prescribe them. The anaesthetic drops wear off after 20 minutes and the dilating drops after 3 – 4 hours.

C: Mobility assessment (20 minutes):

Assessment of movement by a physiotherapist.

D: Questionnaires to be completed by a parent (60 minutes at the time of the Cognitive Assessment)

The questionnaires will cover:

- The impact of your child's developmental strengths and difficulties on independence at home, in school, and in the community.
- Support from health, community, educational and social care services
- Details of your employment and time off work due to your child's health.

E: MR Imaging: (Scanning time 30 minutes)

MRI scans use strong magnetic fields and radio waves to produce a detailed image of the inside of the body. The device that carries out MRI scans is known as an MRI scanner. The scanner consists of a large tube that contains a series of powerful magnets. The participant lies inside the tube during the scan. Due to the way MRI works, an MRI scanner can provide very detailed images of the brain.

The children will be able to see and practice lying in the MR scanner beforehand if they feel worried about it. Parents will be able to be present in the scanning room. The children will need to lie still for a short period for standard images, whilst watching a video. The scanner makes knocking noises which will be filtered out with protective headphones (with music/video). The child is able to communicate with the scan operator to pause as they wish.

Functional MRI will also be performed where the children will be asked to perform simple tasks like looking at pictures or responding to verbal instructions whilst scanning is in progress to help us to see which areas of the brain become active during these tasks. The total scanning time will be 30 min, with additional breaks in between as required by your child. The scanning procedures will be individualised to each child's abilities and tolerance.

Who decides whether my child takes part?

It is your and your child's decision whether or not to take part in this study.

Are there any risks in taking part?

There are no risks to taking part in this research. Extensive research has been conducted into whether the magnetic and radio waves that are used in MRI scans could pose a risk to the human body. No evidence that there is a risk has ever been found. This means that MRI is one of the safest medical procedures currently available. The MRI scan may be uncomfortable for individuals that have a fear of confined spaces. If your child has any metal implants the MRI scan will not be possible, but your child will still be able to join in with the other assessments. We will go through an MRI safety check list to make sure that any surgically implanted devices (like shunts and reservoirs) are safe in the magnetic field of the MRI scanner.

In the extremely unlikely event that an unexpected abnormality is found on MRI or during the visual assessments a referral will be made to the appropriate Children's Specialist and your GP will be notified.

Are there any benefits in taking part?

This study will not benefit your child directly but will help us learn more about the outcome of intraventricular haemorrhage (IVH) in premature infants with the aim of understanding this condition better and improving treatment in the future.

What happens if I decide my child can take part?

The DRIFT research coordinator (Dr Sally Jary) will contact you by your preferred method of communication in 7 days' time. At this time you can let us know if your child would like to participate or not. We are happy to answer any questions and to accommodate any special needs or requirements that your child may have.

If you do decide that your child can take part in the study you will be asked to sign a consent form. We will perform assessments of vision and cognitive function and perform an MRI brain scan. We will ask you to complete questionnaires about your child's strengths and difficulties as well as use of health and other support services. These assessments will take around 3 hours (with breaks for drinks and rests) and will be performed at the CRIC centre at St Michael's Hospital (Bristol). We'll also ask permission to access your child's GP, community and hospital health records, to enable us to get a detailed picture of all the treatments and tests that have been needed since discharge from hospital as a baby. Travel expenses will be reimbursed and lunch, drinks and snacks will be provided on the day. Your child will receive a gift voucher as a small token of thanks for their contribution to the research.

What happens if I decide my child should not to take part or if I change my mind about my child being in the study?

If you do not wish for your child to participate in the study no further information will be collected.

If you decide your child can participate you are still free to withdraw your child at any time, including at a much later time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of medical care your child receives in the future.

What information will be collected about my child?

We will ask for your permission to:

- obtain information from your child's teacher/school about any special educational needs and the results of their national curriculum assessments (Key Stage 1 SATS) if they attend a mainstream school.
- access your child's GP, community child health and hospital notes to gain information about use of health services since birth.
- allow the researchers to have access to hospital, community child health, GP records and national curriculum assessments in the future to gain information about ongoing health and education service use.

What will happen to the information collected?

All information collected about your child during the course of the study will be kept strictly confidential, and used for the purposes of the study only.

When the study results are published no child taking part in the study will be identifiable.

If you consent for your child to take part in the study any of the information collected or their medical records may be checked by authorised individuals from the University of Bristol (who are organising this research study) or University Hospitals Bristol NHS Foundation Trust to check that the study is being carried out correctly.

Who reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect the safety, rights, wellbeing and dignity of participants. This study has been reviewed and approved by NRES Committee South West – Central Bristol.

**We hope that this leaflet answers your questions. If you have others, please contact one of the research team at the address below.
Thank you very much for helping us with the development of this study.**

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