

CATNAP: The Childhood Ataxia Telangiectasia Neuroimaging Assessment Project



Name of Investigators: Dr RA Dineen, Dr W Whitehouse, Dr G Chow, Dr F Raschke,
Prof DP Auer

Study Information Sheet

We would like to invite your child to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you and your child. One of our team will go through the information sheet with you and answer any questions you have. Please take time to read the following information carefully and discuss it with family members, friends or health professionals if you wish to.

We encourage you to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish for your child to take part. You are welcome to keep this leaflet. Thank you for reading this.

What is the purpose of the study?

Ataxia-telangiectasia (A-T) is a rare inherited condition. Children and young people with A-T develop neurological symptoms such as abnormal movements and difficulties with walking and speech. These neurological symptoms result from irreversible changes in the brain tissue structure called *neurodegeneration* (or ND for short). This particularly involves the back part of the brain – the cerebellum. Although there are treatments for some of the symptoms of A-T, there is no effective treatment for the underlying progressive ND.

State-of-the-art magnetic resonance imaging (MRI) scans can allow us to measure a variety of different biological processes in the brain, and we believe that some of these MRI measures (called *MRI biomarkers*) have the potential to improve our ability to detect and monitor ND in children and young people with A-T. Biomarkers

are very important for the development of A-T treatments because 1) they help us understand the A-T disease process and 2) they allow us to effectively assess whether or not a treatment or drug works.

This study is therefore an important first step towards understanding how potential MRI biomarkers of ND relate to neurological symptoms in A-T. Once completed, this study will allow us to select the most promising MRI biomarkers of ND in A-T to take forward into future MRI and treatment trials.

What does the study involve?

The study involves a single visit to the Queen's Medical Centre in Nottingham. During the visit your child will undergo an MRI scan of the brain. With the MRI scan we will gather information about the brain structure and function. This scan is harmless and has no side effects, and will last around 40 minutes.

Why has my child been invited to take part?

This study aims to identify changes on brain scans that relate to neurodegeneration in children and young people with A-T compared to children and young people that do not have A-T. We are inviting your child to take part as a healthy control. We are also inviting 30 children and young people with A-T and 20 other children and young people without A-T to take part.

Does my child have to take part?

It is up to you and your child to decide whether or not to take part. If you do decide that your child can take part you will be given this information sheet to keep. You will also be asked to sign a form giving your consent for your child to take part. If you decide for your child to take part they can still be withdrawn from the study at any time and without giving a reason, if you wish.

What does my child have to do?

If you are interested in participating, then please contact the CATNAP research team via email (CATNAP@nottingham.ac.uk), or using the reply slip at the end of this leaflet. You will then be contacted by one of the research team members who will briefly check your child's suitability for the study and will arrange an appointment at the Queen's Medical Centre, Nottingham.

As your child is under 16 years of age, to help to prepare them for the MRI scan, we will send you an internet link to an animated film that explains what happens when you have an MRI scan. As this is a new film produced especially for the Queen's

Medical Centre we would like to ask you and your child for your thoughts on the film, and whether it helped in preparing for the scan.

On arrival at the Queen's Medical Centre you will be met by one of the research team and taken to the clinic room. The researcher will explain what will happen to your child during the visit. You will be asked to sign the consent form, or if you have already signed this you will be asked to confirm that you are still willing to participate. Your child will also be asked if they would like to sign the consent form as well, stating their willingness to participate.

You will then be taken to the MRI scanning facility. On arrival at the MRI facility, one of the research team will ask you to complete the MRI scan safety questionnaire. To help to prepare your child for the scan, one of the research team members will tell your child about the scan and will explain, in a child friendly and reassuring manner, what they will see and hear during the scan. You and your child will be shown around the scanner and scan room, so that your child can get used to the environment. Your child can bring along a favourite cuddly toy (but without batteries, metal parts or electronics, please!) that they can use for a 'dress-rehearsal' of the scan, and that they can take in with them when they have their proper scan. After the preparation session, there will be a chance for a break before you return for the proper scan.

Before you and your child enter the scan room the researcher will check that you have removed all jewellery and loose metal. For the proper MRI scan your child will lie in the MRI scanner for a period of around 30 minutes while we acquire the brain scan images. Your child will have to lie on their back within the MRI scanner, and we have soft pads and blankets to help them get comfortable. While in the scanner your child will have protective earplugs or earphones on as MRI scanners can be very noisy. If your child becomes upset they will be able to contact the MRI technician during the scan via an intercom or with an emergency buzzer.



The MRI scanner at QMC that will be used for the study

As parents/guardians you will have the opportunity to be with your child during the scan in the scan room if you wish. Our experienced staff will be present at all times and closely monitoring your child during the MRI scans. After the MRI examination you can go home.

If your child is aged 12 years or younger we will contact you by email (or by post if preferred) around three months after the scan to briefly find out what your child thinks about their experience of having the MRI scan. This information is useful to us as it helps us to improve the experience of MRI scanning for children participating in research.

What are the benefits of taking part?

There are no direct benefits for you or your child in taking part in the study. However, the study aims to advance our understanding of how and when changes in the brain occur in children and young people with A-T, and how these changes relate to the development of abnormal movements and other neurological features in A-T. We hope this information will be useful in the future for helping to develop and monitor treatments for these problems in children and young people with A-T.

What are the possible disadvantages and risks of taking part?

Provided your child does not have a condition which prevents them from having an MRI scan, there are no risks associated with this study. Your child will be screened for conditions preventing them from having an MRI scan before they have the scan.

The MRI scanner is a relatively enclosed space and some children may feel claustrophobic. During the scan they will be able to speak to the researchers performing the scan.

There is a small chance that your child's brain scan may show an unsuspected abnormality that is relevant to their health. If a possible abnormality is seen by a member of the research team, we will inform your child's general practitioner (GP) so that further investigations can be arranged.

Expenses and payments

Travel expenses will be offered to participants and families incurred as a result of participation.

What if something goes wrong? Who can I complain to?

In case you have a complaint on your child's treatment by a member of staff or anything to do with the study, you can initially approach the lead investigator. If this route fails to achieve a satisfactory resolution and you still wish to complain about any aspect of the way that you or your child have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms may be available to you. The Patient Advice and Liaison Service (PALS) can be contacted for further assistance at QMC by calling 0800 1830204

Will my child's taking part in this study be kept confidential?

Yes. All information which is collected about your child during the course of the research will be kept on a password protected database and is **strictly confidential**.

What will happen if my child does not want to carry on with the study, or if I want my child not to carry on with the study?

Your agreement for your child to participate is voluntary and you are free to withdraw your child at any time, without giving any reason, and without your legal rights being affected. If you withdraw your child then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

Your child's GP will be informed of their participation in this study.

What will happen to the results of the research study?

We will not be able to make the results of individual scans or assessments available to participants, but we will be happy to let participants know the outcome of the study once the analysis is finished. A tick box has been included on the consent form for you to tick if you would like to be informed of the outcome of the study. Your child will not be identified in any report or publication. It is hoped that the results will be used to guide further research looking at treatment strategies of children with A-T. We are already planning follow-on studies looking at how A-T affects the brain over time, and if you choose to participate in the CATNAP study then we would like to seek your permission to contact you in the future for any studies that follow on from the CATNAP study.

Who is organising and funding the research?

The study is being organised by members of the Division of Clinical Neurosciences, University of Nottingham, and the Nottingham Children's Hospital, which is a part of the Nottingham University Hospitals NHS Trust.



The study is jointly funded by a grant from the Ataxia Telangiectasia Children's Project and Action for A-T.



This study is supported by the Ataxia Telangiectasia Society.



Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Derby NHS Research Ethics Committee.

Contact for Further Information

If you would like to discuss the study further or would like more information, please feel free to contact us by email (CATNAP@nottingham.ac.uk), post or telephone:

Dr Rob Dineen

Clinical Associate Professor
Radiological Sciences
University of Nottingham
Queen's Medical Centre
Nottingham
NG7 2UH

Phone: 0115 8231173

General information and useful links regarding participation in clinical research is provided by the People in Research website: <http://www.peopleinresearch.org/?o=1192>

If you would like your child to participate, or would like more information, contact the CATNAP team by email (CATNAP@nottingham.ac.uk). Alternatively, please complete and return this form to the address above.

Name:

Address:

.....

.....

.....

.....

Telephone:

Email:

Please tick box as appropriate:

☐

I have read the information leaflet and would like my child to participate in the study. Please contact me to arrange an appointment to visit the hospital. (if you tick this box you are, of course, free to withdraw from the study at any time.)

I would prefer to be contacted by (please tick one):

☐

By telephone

☐

By email

If you would like to be contacted by telephone, please state your preferred time to be contacted (delete as appropriate):

Morning / Afternoon / Evening / No Preference

Please detach this form and return it to the address above. Many thanks.