Head injury Evaluation and Ambulance Diagnosis: A Feasibility Study

Study Participant Information Sheet (PIS)

You are being invited to take part in a research study to find out if paramedics could use the Canadian CT head rule to find out which patients need a brain scan before they go to hospital. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➢ Who will conduct the research?

This study will be conducted by Naif Alqurashi for his PhD degree at the University of Manchester. Naif is working under the supervision of Professor Richard Body, Professor of Emergency Medicine at the University of Manchester and Professor Fiona Lecky, Clinical Professor of Emergency Medicine, the University of Manchester.

➢ What is the purpose of the research?

Most people who suffer a head injury have no serious damage to their brain or skull. However, a small number of people will have serious damage and some people will need an operation. It is often difficult to tell which patients have a serious head injury and which patients do not.

At the moment, when an emergency ambulance is sent to patients who have a head injury, they will take all patients to hospital. In hospital, some patients will need a brain scan (a CT scan). However, most do not. Doctors in hospital use a checklist called the Canadian CT head rule to decide if a brain scan is needed. Research in thousands of patients have shown that this is safe.

We want to find out if paramedics could use the Canadian CT head rule outside the hospital to find out which patients have only a mild injury and do not need to have a CT scan. If they can do that accurately then many patients could safely avoid a trip to hospital, where there are often long waits. In this study we will look at how accurate the Canadian CT head rule is, we will find out how often

paramedics and doctors in hospital agree with each other when applying the Canadian CT head rule, and we will see if it will be possible to carry out a future large research study to check how safe it would be for paramedics to use the Canadian CT head rule.

➢ Am I suitable to take part?

You have been invited to take part in this study because your paramedic might suspect that you may have a head injury requiring further tests at a hospital. The Canadian CT head rule is designed to be used in situation like this.

➢ Will the outcomes of the research be published?

It is expected that the results of this research will be published in a medical journal by 2024, allowing a larger number of individuals/researchers to benefit from the findings. The identities of all participants in the study will be kept confidential. In addition, the data from this study will be submitted for the degree of Doctor of Philosophy (PhD). We would be happy to provide you with information regarding the results if you are interested. When the results are available, we will write to you.

➢ Who has reviewed the research project?

This study has been reviewed by the supervisory team at the University of Manchester. We have obtained ethical approval from the National Research Ethics Committee; REC reference xx/xx/xx and the Health Research Authority.

What would my involvement be?

➢ What would I be asked to do if I took part?

If you agree to take part, the medical care you will not be delayed or changed in any manner. Your paramedics and the hospital staff will record clinical information on a case report form that is necessary to use the Canadian CT head rule. The research team will analyse these data to evaluate the possibility of using the Canadian CT head rule by paramedics in the future. It is with your permission that members of the study team and the NHS Trust will access your medical records in order to collect information for the study and information regarding your medical history. With your consent, we will inform your GP about your participation in the study.

You may also be asked to participate in an interview to ask you about your personal experiences of being involved with this research. By sharing your experience, we will be able to plan a large study that examines the effectiveness of this rule when used by paramedics. The interview will last no longer than 60 minutes, and we will audio record it with your consent. We also provide the option of doing a phone interview, and language interpreters will be provided as requested. We can offer you a £30 high street voucher to thank you for taking part in the interview. If you agree to take part, we will provide further information in a separate information sheet, and later we will obtain your consent for this. If you wish to take part and would like to talk about the date and time of the interview, please contact: Naif Alqurashi

Naif.alqurashi@postgrads.manchester.ac.uk – 07877711705).

- **Will I be compensated for taking part?**

There are no immediate benefits for individuals who participate in this study. We anticipate that the findings of this study will help to improve the care we provide in the future by providing clinical evidence to conduct further studies in this area.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will need to sign a separate consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. Opting out will remain possible until 30 days after your agree to take part in this study. It will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research project, we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect:

- Your name

- Gender
- Date of birth and age
- Phone number and/or email address
- Ethnicity
- Record of consent
- Information about the incident
- Relevant past medical history

➢ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

➢ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research

https://documents.manchester.ac.uk/display.aspx?DocID=37095

➢ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The study team at The University of Manchester and research nurse at [INSERT TRUST NAME] will have access to your personal information, which will be anonymised within 30 days of your consent to participate in this study. Your name and any other identifying information will be removed and replaced with a random ID number. The research team will have access to the key that

links this ID number to your personal information. Your consent form will be retained for 5 years in a locked cabinet on UoM premises for audit purposes.

With your permission, we will use your contact details to contact you in order to arrange an interview for the purpose of asking you about the study.

Your completed paper case report forms including your personal information will be retained for 5 years to comply with regulations and stored securely in a locked filing cabinet at [INSERT TRUST NAME] in keeping with local NHS Research & Development protocols.

If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/

At the end of the project we will deposit a fully anonymised dataset [e.g. including de-identified interview transcripts] in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

Unless you opt-out, we will let your general practitioner know about your involvement in the study. Please also note that individuals from The University of Manchester, [INSERT TRUST NAME] or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester [or include names of other organisations e.g. the NHS Trust] but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you. The University of Manchester will arrange insurance for research involving human subjects that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University of Manchester, subject to policy terms and conditions.

➢ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact: Prof Richard Body (Lead Investigator), Emergency Department, Manchester Royal Infirmary, M13 9WL, Manchester, Email: richard.body@mft.nhs.uk, Tel: 0161 276 5071, Secretary: 0161 276 8539

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information

https://ico.org.uk/make-a-complaint/ -Tel 0303 123 1113

➢ Additional information in relation to COVID-19

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

➢ Are there any additional considerations that I need to know about before deciding whether I should take part?

While you are attending A&E routine precautionary measures are in place across the hospital site to mitigate the risks related to COVID-19. Those include but are not limited to social distancing, wearing face masks (PPE) and routine cleaning

and disinfection of surfaces and equipment. If you are part of a vulnerable group or think you have COVID-19 symptoms you should opt-out from participation.

- **What additional steps will you take to keep me safe while I take part?**

When signing the consent form, we recommend using a personal pen if available or will provide one that has been disinfected before use. In the event that you agree to participate in an interview, it will be conducted remotely, thus eliminating any further risk to you.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researchers

- **Professor Richard Body (Lead Investigator), Emergency Department, Manchester Royal Infirmary, M13 9WL, Manchester, Email: richard.body@mft.nhs.uk, Tel: 0161 276 5071, Secretary: 0161 276 8539**
- **Naif Alqurashi, Division of Cardiovascular Science, Faculty of Biology Medicine and Health, The University of Manchester, M13 9NT, Manchester, Email naif.alqurashi@postgrad.manchester.ac.uk**