SHED PATIENT INFORMATION SHEET V1.1

STUDY TITLE

Subarachnoid Haemorrhage in the Emergency Department: SHED
Chief Investigator: Dr Dan Horner Local Principal Investigator:

1. INTRODUCTION

The SHED study aims to understand how acute headaches are dealt with by the Emergency Department (ED). This study doesn't involve any additional treatments or tests, and no extra questions other than those that your Doctor will ask you routinely. We aren't seeking written consent for this study because it involves no change to your clinical assessment or care. However, if you don't want to take part it is easy to opt-out as described below.

2. WHY HAVE I BEEN INVITED TO TAKE PART?

You are being invited to take part because you have attended the ED with an acute headache.

3. WHAT IS THE PURPOSE OF THE RESEARCH?

This research aims to evaluate different strategies for investigating serious causes of headache. In particular, we are looking carefully at those patients who go on to have a scan of their brain and whether the timing of this affects the need for further investigations.

4. WHAT WILL HAPPEN IF I TAKE PART?

We will collect data from your medical records about the features of your headache, and the examination findings. We will also record the investigations you had whilst in hospital and the diagnosis provided. We will then review your records one last time at 28 days, to ensure that you have not had a different diagnosis or headache related condition recorded since hospital discharge. To take part in the study you don't have to do anything. The information we need is the information you will be providing to your Doctor during your routine care. We won't need to ask you any further questions, either today or at a later date. However, we will check your hospital and GP medical records to check that you weren't re-admitted to a hospital with headache for a 4-week period after today.

5. DO I HAVE TO TAKE PART?

No. If you decide you don't want to be involved in this study, this will not affect your medical care in any way. You can simply tell the Doctor or Nurse seeing you during this attendance, or you can contact the research team by email or telephone at a later stage to let them know. The contact details are at the bottom of this sheet. You do not need to give a reason. Even if you don't initially opt out, you are free to change your mind and withdraw at any stage.

6. ARE THERE ANY PAYMENTS OR EXPENSES FOR THIS STUDY?

No, there are no associated payments or expenses by being involved in this study.

7. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

There will be no direct benefit to you by taking part. However, this research may change the way that headaches are managed in the future and therefore impact on your future treatment if you re-attend. It could also positively impact someone who comes to the hospital with the same problem as you.

8. WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Your doctor *may* decide you need a CT Brain and/or CT angiography as part of your routine care. If you take part in this study you will not undergo any additional x-ray imaging. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to you are the same whether you take part in this study or not. There is also a risk within the study of data storage. We have minimised this risk through use of a specialist medical database service which conforms to all current international standards. We are treating this project like any serious research study, with strict oversight and regular review.

9. WHAT ABOUT CONFIDENTIALITY?

We will need to use information from you, your medical records and your GP for this research project. This information will include your NHS number name and date of birth. The research team will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. You can stop being part of the study at any time, without giving a reason, and we will delete information about you that we already have. We will not collect any further data about you. You can find out more about how we use your information:

@ https://bit.ly/2qbf7hf | Our leaflet @ https://bit.ly/2qV1aUs | By asking one of the research team (details below) | By contacting the Northern Care Alliance NHS Group Data Protection Officer DataProtection.Officer@srft.nhs.uk | By viewing the Sponsor's privacy link @ https://bit.ly/33kekYJ.

10. WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The final outcomes from the study will be communicated via presentations in scientific meetings and by peer reviewed publications. Updates are available https://bit.ly/33YepSY. We will aim to publish the results approximately 12 months after completion.

11. WHO IS ORGANISING AND FUNDING THE RESEARCH?

The research is organised by the research team at Salford Royal Foundation Trust. The research is funded by Royal College of Emergency Medicine and management oversight (Sponsorship) is provided by Salford Royal Foundation Trust.

12. WHO HAS REVIEWED THIS STUDY?

We can confirm that the study has been reviewed and approved by an appropriate NHS Research Ethics Committee, (Research Ethics Committees South West - Frenchay).

13. WHAT IF THERE IS A PROBLEM?

If taking part in the study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you have a concern about any aspect of the way you have been approached or treated during this study, you should speak to the researchers who will do their best to answer your questions (see contact details below). If you have any complaints about the treatment you have received as part of this study, you can also contact the hospital PALS (Patient Advise and Liaison Services) team. If you have any questions about this research please write to us or contact us using the details below. Thank you for taking the time to read this information sheet.

Site: [HOSPITAL] Principal Investigator: [NAME]
Research Team contact details: [EMAIL@EMAIL.COM] / [PHONE NUMBER]