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ASTEROID

Participant Information Sheet

Assessment of Surgeon Treatment Equipoise & Randomisation Opinion to Inform trial Design in umbilical hernia research (ASTEROID)

Version 1.1 (28-Feb-2025)

1. Invitation and brief summary

We would like to invite you to take part in the ASTEROID study, run by the Birmingham Centre of Observational and Prospective Studies (BiCOPS), based at the University of Birmingham (study sponsor) and University Hospitals Birmingham. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it will involve for you. A member of our research team will go through this information sheet with you, to help you to decide whether or not you would like to take part and to answer any questions you may have. Please feel free to talk to others about the study if you wish.

This Participant Information Sheet (PIS) tells you the purpose of the study, what will happen to you if you take part and detailed information about the conduct of the study. Please do take the opportunity to ask any questions you have and to ask for more information if anything is unclear.

2. Purpose and background to the research

We know that every year in the UK around 3,000 people will have an emergency operation on an umbilical (belly button) hernia. Surgeons can fix this hernia by using stitches, or by using a mesh to help rebuild the weakness in the muscles. Both repairs are safe and give good outcomes. However, we don't know if one is better than the other. It's important that surgeons offer people the best repair overall, and we want to help them do this.

We often focus on complications after surgery to work out if an operation is good or not. This means things like infections, wound problems, and the chance that the hernia comes back. We don't have much information on things that matter to patients. There are questionnaires that help us to look at how treatments impact on symptoms daily activities. We need to know more about how our operations affect these.

To work out which operation is better overall, we need to do a trial to compare them. This trial is likely to be large and there are some things we want to work out before we start it. This study you have been invited to participate in will help us design that bigger trial.

The key things we want to find out are:

- How long it would take to get enough patients into a big study
- How many people would keep telling us about their outcomes after surgery
- In which operations surgeons would be willing to offer either treatment

To do this, we are asking up to 100 patients to take part in this initial study where we will watch and collect data on what happens during their admission, ask their surgeons about the different repairs, and ask the patients to complete some questionnaires online after their operation.

3. Why have I been chosen?

You have been invited to take part in this as you have an umbilical (belly button) hernia that needs an emergency operation.

4. What would taking part involve?

This study is 'observational'. This means that we watch what is happening in your care and do not change anything about it. You and your surgeon will make decisions about your treatment.

If you decide to participate, you will be asked to complete a consent form to say that you agree to take part. We will collect some basic information about you such as your age and sex and will also record information about your hernia. Before your operation, we will ask you to complete two questionnaires which look at quality of life, and hernia specific symptoms. This will take 5-10 minutes in total. We will also ask for your email address to send questionnaires to after surgery.

When you have your operation, we will ask your surgeon for some technical information. We will also ask them to imagine that you are in a randomised trial, and ask whether they would have given you a treatment chosen randomly by the research software. This will not change your care as it is done at the end of the operation.

Most people go home within a day or two of surgery. We will send you an email at day 7 after your operation to ask you to fill in three questionnaires. Two of these surveys are the same as you completed before your operation, on general quality of life and hernia specific symptoms. The third survey asks about wound problems. We will send you a reminder email the day after this and for the following 2 days if you haven't completed the questionnaires. We will email you again at 30 days after your operation with the same questionnaires and remind you complete them in the same way. We will ask your surgeon to tell us if you came back to hospital within a month for problems related to your operation.

5. What are the possible benefits of taking part?

There are no direct benefits to you or other participants. Taking part will help to move us closer to a study to work out the best way to treat this type of hernia, and so there are wider benefits to society and potentially to future patients with umbilical hernia.

6. What are the possible disadvantages and risks of taking part?

This study should cause minimal burden to participants. We are not changing care. There is a small amount of time (10-15 minutes) needed to complete the questionnaires prior to your surgery and again at day 7 and day 30 post surgery. There are no other disadvantages.

7. Who is sponsoring, organising and funding the research?

This study is being led by researchers at the University of Birmingham. It has been funded by the British Hernia Society. Your surgical team are not paid for delivering this study. The research team do not have any conflicts of interest, such as relationships with industry, that might influence study design. The University of Birmingham is the study sponsor.

8. How have patients and the public been involved in this study?

We have worked with patients to design this study. They have helped us to choose the patient surveys, and provided feedback on this patient information sheet. In designing this study we

have taken into account patient opinions on the frequency of participant involvement and the assessments that we will carry out.

9. Who has reviewed the study?

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

10. How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name and email contact details. People will use this information 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.

The University of Birmingham is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Restricting access to your information to just those who need to see it; typically the ASTEROID research team at your hospital and the University BiCOPS study management team running the study. Sometimes the sponsor or regulatory bodies may wish to review conduct of a study and request access to data. These are the only groups outside the research team who may have direct access to the database.

- Your data is stored on a database at the University of Birmingham. This database is encrypted, and access requires personal passwords and two-factor authentication to take place.

- All activity on the database is logged, so we can see who has added and viewed your data.

Your data will not be shared outside the UK.

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. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymized and securely archived.

11. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

12. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- Our leaflet: http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to the University of Birmingham Data Protection Officer: dataprotection@bham.ac.uk

13. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS). Your local PALS team can be contacted by telephone <localised number> or email <localised email address>

14. What if I do not want to take part?

You do not have to take part in this study. Participation is up to you. Whether you participate or not, your surgeon will provide the same care around your operation. The main difference is that you will not be asked to complete surveys on symptoms or quality of life after treatment.

If you start to participate but then change your mind afterwards, please inform the study management team. Details of how to contact them are at the end of this information sheet. We would normally ask to keep any data we have already collected about you.

15. Will my travel expenses be reimbursed?

There are no additional visits to hospital scheduled in this study.

16. What happens when the research study stops?

At the end of the study your surgeon will continue to look after you and your treatment if this is needed.

17. What will happen to the results of the research study?

We will use the findings of this study to inform the design of a randomised trial. We may present the findings at a scientific meeting and publish them in a scientific journal. When we do this, we make sure study participants are not identifiable. We do this by reporting as an overall group, or according to treatment received, or other relevant groupings.

With your permission, we will share the findings with you at the email address you use during the study. This will be in the form of an email or a short video.

18. How will my personal data be kept secure?

The University of Birmingham takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

Any physical paperwork containing identifiable data will be kept in an access-controlled and secured room inside a locked filing cabinet.

In relation to this project, electronic data will be kept on secure, encrypted IT servers within the University of Birmingham.

19. How long will my personal data be kept?

Your data will be retained for 10 years after publication of research findings, as per the University of Birmingham Code of Practice for Research.. If you withdraw from the project, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally-identifiable information possible.

20. Do you have any further questions?

If you have further questions about the study, please ask your local research team, contact details are given below. If you have concerns about the study, please email the study team on bhamred@contacts.bham.ac.uk.

<Contact Information (for localisation)>

If you would like to speak to someone in the BiCOPS team at the University of Birmingham about ASTEROID please contact:

Dr Michala Pettitt, Research administrator

bhamred@contacts.bham.ac.uk

Support can also be found through *<NHS Patient Advisory and Liaison Service (PALS); or local equivalent>*

Tel: *<insert local PALS contact number(s)>* Email: *<insert local PALS email address>*