

SARC

Salbutamol for Analgesia in Renal Colic: A prospective, randomised, placebo controlled Phase II trial

IRAS ID: 252075

Participant Information Leaflet

SARC Study

We would like to invite you to take part in a research study. Before you decide whether or not to take part, your medical team will go through this patient information leaflet with you. They will answer any questions you may have so that you fully understand why we are running the study and what it would involve for you.

Please take the time to read the information carefully and talk to others about the study if you wish. Ask your doctor or nurse if there is anything you don't understand or if you would like more information. Please take your time to decide whether or not you wish to take part.

You are free to decide if you want to take part in this research study. If you choose not to take part this will not affect the usual care you receive in any way.

You can decide to stop taking part in the study at any time without giving a reason. If you decide to take part, we will ask you to sign a form to give your consent for the study.

Contents

- | | |
|--|---|
| 1. What is the purpose of the study | 9. What happens when the study stops? |
| 2. Why have I been invited? | 10. What if there is a problem? |
| 3. Do I have to take part? | 11. Will my participation in the study be kept confidential? |
| 4. What will happen to me if I take part? | 12. What will happen to the results of the research study? |
| 5. What will I have to do? | 13. Who has reviewed this research? |
| 6. Expenses | 14. Who is organising and funding the research? |
| 7. What are the disadvantages and risks of taking part? | 15. Contacts for further information |
| 8. What are the advantages of taking part? | |

1. What is the purpose of the study?

Renal colic is the name for the pain experienced when a kidney stone causes a blockage in the tube between the kidney and the bladder.

Standard pain-killers do not always work and are also associated with side effects such as vomiting or drowsiness. Previous groups of patients who have experienced renal colic have described how bad the pain from renal colic can be, how long the pain-killers take to be effective, and how unpleasant the side effects can be.

It is thought that salbutamol, a drug commonly and successfully used to treat asthma, may reduce the pain of renal colic. It has few side effects.

This study will investigate whether adding salbutamol to the normal pain relief given to patients with renal colic leads to better pain control.

2. Why have I been invited?

You have been invited because you have pain in your abdomen or flank and your medical team suspect that you may have renal colic.

3. Do I have to take part?

No. It is up to you to decide whether to take part. Even if you decide to take part, but change your mind at any time, you will be free to withdraw at any time and without giving a reason. Your usual care will not be affected in any way whether or not you take part, or even if you take part and then decide to withdraw. If you do withdraw from the study, we will keep any information relating to the study which has been collected about you up to that point. This information will, however, be anonymised so that you will not be identifiable from it in any way.

If you do decide to take part, we will ensure that you understand all the information provided, and you will then be asked to sign a consent form. You will be given a copy of the signed consent form to keep, as well as a copy of this information leaflet.

4. What will happen to me if I take part?

Routine assessments to determine whether you are experiencing renal colic will continue and you will be given the usual pain relief as part of normal medical care. We may need to do an ECG (a heart tracing) and a blood test to ensure you are eligible to take part; this will happen only if you haven't already had these done and you wish to take part in the trial. We will not keep the blood sample we take once it has been processed.

If you are found to be eligible to take part then a doctor will discuss the study with you. During this time you will have the opportunity to ask any questions or discuss worries you may have. After this, should you wish to take part, you will be asked to sign a form to say that you consent to be part of the study. Once you have agreed to take part, we will make arrangements for you to start the study medication.

In this study one group of patients will receive usual standard care for their pain (according to the best way we know how at the moment) and placebo (salty water that's safe for injection) and the other group will receive the same standard care and intravenous salbutamol (into a drip). This lets us compare the results between the two groups to see which is better. To try and make sure the groups are the same to

start with, each patient is put into a group by chance (randomly, like the toss of a coin). You will have a 50:50 chance of being allocated to the salbutamol group, and to minimise the chance of bias neither you nor the team looking after you will know which treatment you receive.

The study will take place over a 24 hour period. During this time you will have regular observations taken at the time the trial drug is given and then at 15 and 30minutes, 1, 2, 4, 8, 12, 16, 20 and 24 hours. If you are ready to go home from hospital sooner than 24 hours then the study will finish at this time; you will not be kept in hospital longer than would normally be necessary due to participation in this study.

5. What will I have to do?

You will be asked to answer questions about your pain at the time points discussed above. You will also be asked to complete a questionnaire about your involvement in the study.

6. Expenses

Taking part will not cost you anything, and no payments will be made as a result of this trial.

7. What are the disadvantages and risks of taking part?

The risk of taking part in the trial is no higher than the risk of standard medical care.

Salbutamol is a commonly used drug with few significant side effects. A number of people who are given salbutamol will be shaky, have a fast heart-beat, develop a headache or have muscle cramps. These side effects are usually mild, and are always short-lived.

If you are pregnant, breast-feeding or trying to get pregnant then please inform the research staff as it may not be appropriate for you to take part in the trial.

If you are asthmatic and have taken your inhaler in the last 6 hours, please let a member of trial staff know.

8. What are the advantages of taking part?

We cannot be certain that there will be any advantages to you being in the trial, although salbutamol may reduce the pain of renal colic. We hope that the information gained from this trial will help future patients with renal colic.

9. What happens when the trial stops?

The routine clinical care of both you and other people will not be affected in any way. Your pain will be investigated and any necessary follow-up arranged exactly as if you had not taken part in the trial.

10. What if there is a problem?

If you have any concerns or queries about any aspect of this study you should ask to speak to one of the research team or your Doctor who will be undertaking the day-to-day running of the study and who will do their best to answer your questions.

We don't expect it to, but in the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for legal action against University Hospitals of Derby and Burton NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

If you wish to complain about the conduct of the research you should contact Dr Graham Johnson, Department of Emergency Medicine, Royal Derby Hospitals, University Hospitals of Derby and Burton NHS Foundation Trust, Derby, DE22 3NE. Telephone 01332 340131

Alternatively, if you wish to speak with someone not involved in the study, you could contact the Patient Advice and Liaison Service (PALS) on:

Freephone: 0800 783 7691
Email: dhft.contactpals@nhs.net
Text: 07799 337500

11. Will my participation in the study be kept confidential?

Yes. We will follow all relevant ethical and legal practices and all information collected about you during the course of the research will be handled confidentially. It is necessary to record in your hospital notes that you are participating in this study, for your benefit and protection. The team at University Hospitals of Derby & Burton NHS Foundation Trust (UHDB) will work according to the Data Protection Act 2018 and the General Data Protection Regulations (GDPR).

UHDB is the sponsor for this trial and will act as the data controller. This means that we are responsible for looking after your information and using it properly.

The research team will collect information from you and your medical records for this trial in accordance with instructions from us. They will use your name, hospital number and contact details to contact you about the trial make sure that relevant information is recorded. You will be allocated a study number, and this along with your initials will be the only references that will be recorded about you on our computers.

UHDB will keep identifiable information about you from this trial for 15 years after the trial has finished. To safeguard your rights, we will use the minimum personally-identifiable information possible. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Information about your participation in this study will be sent to your GP.

If you withdraw from the trial, we will keep the information about you that we have already obtained and it will not be possible to identify you from this.

Individuals from UHDB and regulatory organisations may look at your medical records and the information collected about you for this trial. This is to help them check the data collection process and ensure the trial is being carried out as it should be. The people who analyse the information will not be able to identify you and will not be able to find out your name, hospital number or contact details.

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

You can choose to withdraw from the study at any time you wish and without having to give us a reason. If you do, we will need to use the data collected on you up to that point but this will of course be kept confidential and you cannot be identified

from it.. If you choose to withdraw from the study this will not affect your on-going routine clinical care and we will make arrangements for this to be restarted for you.

Once the study is complete its results will be analysed and published in a medical journal, as well as presented at conferences. You will not be identifiable in any of these presentations or publications.

13. Who has reviewed this research?

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 the West of Scotland Research Ethics Committee 1.

14. Who is organising and funding the research?

The study has been designed by a group led by Dr Graham Johnson, Consultant in Emergency Medicine at University Hospitals of Derby and Burton NHS Foundation Trust. It is funded by a grant from the National Institute for Health Research's Research for Patient Benefit Programme.

15. Contacts for further information

Dr Graham Johnson
Emergency Department
Royal Derby Hospital
Uttoxeter Road
Derby, DE22 3NE

01332 340131

Insert Research Team Contact details

Address:

Telephone Number:

Please contact one of the contacts above or feel free to discuss this study with any health care professional involved in your care.

If you wish to discuss the study with someone independent of the research team you can contact the local NHS Patient Advice and Liaison Service (PALS) on:

Email: dhft.contactpals@nhs.net Phone: 01332 785 156
To find out more about the regulation of Research within the NHS visit:
www.nres.nhs.uk