

1) Why are we doing this trial?

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.

Previous groups of patients who have experienced renal colic have told us how painful renal colic can be, how long the pain-killers take to be effective, and how unpleasant the side effects can be.

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

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

Why am I being asked to take part?

Your doctor believes that you are experiencing renal colic, pain caused by kidney stones, so this makes you potentially eligible to take part in this trial. At the Royal Derby Hospital we treat around 400 patients a year with renal colic. We are hoping that 118 of them will take part in with this trial.

What will happen in this trial?

To discover whether salbutamol can be effective for pain relief, we will randomly put patients in to one of two groups, either to receive salbutamol or placebo (sodium chloride—salty water that's safe for injection). This is done by chance, like the toss of a coin.

2) What will happen if I take part?

If you would like to take part, we will make sure that you have understood this information and asked any questions you may have, and will then ask you to sign a consent form.

- The usual care you would receive as someone with suspected renal colic will continue.

- You will be given the usual pain relief you would expect to receive (you may have already received some of this pain relief).
- You will have an electrocardiogram (ECG—a heart tracing) if you have not already had one. We may also need to take an additional blood test to confirm you are eligible for the study (we won't keep the blood sample).
- We will ask you to complete a couple of questionnaires about your pain, called the McGill questionnaire and a Visual Analogue Scale (VAS).
- The clinical staff looking after you will take a note of your heart rate, breathing rate, and blood pressure, as well as other observations you would normally expect to have taken.
- You will then receive **one** injection over 3-5 minutes, given by hand, of either salbutamol or placebo (salty water).
- You will have a 50:50 chance of receiving salbutamol, and neither you nor the team looking after you will know which treatment you receive.
- The trial will take place over a 24 hour period. During this time you will have regular observations taken and will be asked to answer questions on how bad your pain is multiple times over this period.
- If you are ready for discharge sooner than 24 hours then the study will stop at this stage.

3) Possible advantages and disadvantages of taking part

We cannot promise that taking part in this trial will help you. We think that salbutamol will help with pain relief, but we don't know for sure, and this is why we are doing this trial. We hope that the results of this trial will help us to go on to do a much larger trial to gather more data on this.

Taking part will involve some of your time to fill in the questionnaires about your pain, but you will not be kept in hospital longer than would

normally be necessary due to taking part.

More information on salbutamol is in the next section.

4) About salbutamol

Salbutamol is a well-understood and safe medicine, but it still has some side effects. If it is unsafe for you to take part in this trial or salbutamol would interact with any of your normal medicines then you will not be asked to take part.

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, or think you might be pregnant, are breast feeding or trying to get pregnant, please inform the research team as it may not be appropriate for you to take part.

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

5) More information about the trial

Do I have to take part?

No—it is entirely up to you whether or not you take part in this trial. Saying no will not impact on the usual care you would expect to receive.

What if I change my mind?

Even if you decide to take part, but change your mind either before or after you've received the injection, we will stop collecting information from you. You don't have to give a reason.

What if there is a problem?

If you are worried or have any questions about any part of this trial, you can call the lead investigator, Dr Graham Johnson.

If you want to speak to someone independent, or if you have any concerns or a complaint, you should contact:

- Your local patient advice and liaison service (PALS) on xxxxx

The normal NHS complaints mechanisms are available to you.

We don't expect it to, but in the event that something does go wrong and you are harmed because of the fault of someone, then you may have grounds for legal action for compensation against UHDB, but you may have to pay your legal costs.

Will my GP be involved?

If you agree, we will let your GP know that you are taking part in this trial. There is a box on the consent form for you to sign to agree to this.

Who is organising and funding this trial?

This trial is organised by Derby Clinical Trials Support Unit on behalf of University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) and funded by the National Institute for Health Research (NIHR).

All research in the NHS is looked at by a number of different bodies before it can start, the purpose of which is to ensure that the trial meets ethical and legal standards and the safety, rights and well-being of participants are protected.

This trial has been reviewed and approved by:

- West of Scotland Research Ethics Committee (REC) 1, an independent group or experts and lay members.
- The Health Research Authority (HRA).
- The Medicines and Healthcare products Regulatory Authority (MHRA).

Please turn over

6) What will happen with the information collected about me?

Any information you give us will be kept strictly confidential. 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.
- 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.
- **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.

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

<https://www.uhdb.nhs.uk/research-how-we-use-your-information>.

7) What do I have to do now?

If you have no other questions and are happy to take part in the trial, then you will be asked to sign a consent form.

8) Contacts for more information

If you need any more information, please contact us.

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

Contact details

Chief Investigator: Dr Graham Johnson

Telephone: 01332 340131

Insert Research Team Contact Details:

REMEDY:

Thank you for reading this information.
If you decide to take part, please keep this leaflet.

participant information leaflet



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

We would like to invite you to take part in a clinical trial

Important things you need to know

- This trial is looking at a new way of managing the pain of renal colic (kidney stones)
- People attending A&E with pain that we believe to be caused by renal colic are being asked if they would like to take part in this trial.
- Those who take part will receive routine care as well as an injection of either salbutamol or placebo; which injection they receive is randomly decided.
- We are then asking patients to answer some questions based on their pain levels to help us judge whether salbutamol had any impact on pain relief.
- Participation is completely voluntary and you can change your mind at any time.

Before you decide...

- Please take time to read the following information carefully and discuss it with others if you wish
- Ask us if you are unsure of anything you read in this information leaflet. Our contact details are on the back of this leaflet.
- You are free to decide whether or not to take part. If you choose not to take part, this will not affect any care you may get.

Please turn over to read the full information about the trial

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