RecUrrent Intra-articular Corticosteroid injections in Osteoarthritis: The RUbICOn study

Patient Information Sheet

An interview about steroid injections for osteoarthritis.

1. Invitation

We would like to invite you to take part in an interview (by telephone, or if you prefer by internet video application such as Skype) about your views on intra-articular corticosteroid injections for arthritis, otherwise known as 'cortisone injections' or 'steroid injections'. We'd like to talk to people who have experience of receiving steroid injections for arthritis, as well as people who have not had them. Please take some time to read this information sheet carefully before deciding whether you would like to take part.

2. What is the purpose of the study?

The purpose of the study is to find out about people's knowledge and experiences of steroids injections for arthritis. The study has been commissioned by the NHS, National Institute for Health Research Health Technology and Assessment (HTA) panel. Current evidence for the use of intra-articular corticosteroids for arthritis suggests that they can provide some short-term benefit for pain relief and that there is mild or no evidence of adverse effects. It is expected that the number of people with arthritis will rise over the coming years. This means that it is likely that more steroid injections will be used to treat people with arthritis and that we need more information about any long-term benefits and risks of these injections particularly when more than one injection is used.

We want to talk to people with arthritis, who have experience of having steroid injections, as well as people who have not received them for whatever reason. This is because we want to know about people's thoughts about these injections as well as what they think about any benefits and risks of having them. If you have had one or more injections we'd like to ask you about why you decided to have the injection and whether there was any effect on the symptoms of your arthritis and day-to-day life. If you've had a joint replacement, we'd like to ask you if you had steroid injections before your operation, and whether you feel that they changed how you planned and thought about having your operation. If you've not had any steroid injections for osteoarthritis, we'd like to know whether they are something you know about or had thought about in the past.

3. Why have I been invited? Your GP records identify you as a person with experience of arthritis and this is why we are contacting you. This study is supported by the National Institute for Health Research Clinical Research Network (CRN) West of England, who facilitate research in the NHS and work in partnership with your GP practice.

4. Do I have to take part?
It is entirely your decision whether or not to take part in this research.

5. What will happen if I decide to take part?

- If you agree to take part in an interview you will be asked about your views and experience of corticosteroid injections for arthritis, even if you haven't had them. The interview will be by telephone (or Skype if you prefer). Dr Andrew Moore, the researcher will call you, so you wouldn't have to pay for the call.
- If you would like to discuss taking part please contact Dr Andrew Moore, the researcher conducting the study, by email, text or by telephone. The contact details are at the end of this information sheet.
- If after discussing the study you then agree to take part, an interview can be arranged, by telephone or Skype, whichever you prefer.
- The interview may take up to 60 minutes, but this will depend on how long you're happy to talk for. We will be asking the same questions to everyone who takes part. We are also interested in hearing about anything else about your arthritis and injections that you feel would be helpful or important to tell us about.
- With your consent, we would like to audio-record the interview. This helps us because we can then type it up and have a full and accurate record of what we discussed. We take information security and confidentiality very seriously and adhere to strict data protection guidelines. Any information that could identify you or anyone else is removed from the transcripts. Please see section 10 below for information on how we protect your information.
- Before your interview, we will ask you for your verbal consent to take part and this will be audio-recorded at the beginning of the interview (a copy of the verbal consent form signed by the researcher will be sent to you after the interview). Alternatively, we can send you a consent form by email, which you can complete and return by email.
- We would also like to send you a summary of the results if you tell us that you would like this.

6. When will the interview take place?
If you would like to take part in the study, we can arrange to do the interview at a time convenient to you.

7. What are the potential disadvantages or risks of taking part?

The only real disadvantage to your taking part is the time we would ask you to give up in order to speak with Andrew Moore in an interview. You may find talking about personal experiences upsetting. Should you become upset, we would ask you if you want to stop the interview. You are also free to stop the interview or to decide not to answer any questions without giving a reason, at any time. There may be a risk that you disclose information that relates to professional negligence or malpractice. Any potential cases would be reviewed by a Consultant Orthopaedic Surgeon and Senior GP to determine if further action is required.

8. What are the potential benefits of taking part?

Although this study will not benefit you directly, the results of this study will provide important research information on the use of steroid injections for osteoarthritis, and the development of future research in this area.

9. Can I change my mind and stop the interview once it has started?

Yes. You are free to ask for the interview or the recording to be stopped at any time, or you can choose to stop and then restart at any time, without giving a reason.

10. How will you ensure my details are kept confidential?

Ensuring your data is kept safe is a top priority for the study team. Interviews will be recorded on an encrypted audio-recorder and the recordings will be stored on password-protected computer networks at the University of Bristol and sent to a University of Bristol approved transcription company to be transcribed. The University of Bristol has a number of transcription suppliers who have confidentiality agreements in place. The transcription will then be anonymised by the researcher who will remove any information that could potentially identify you or anyone else (names, places, dates), before analysis is conducted.

With your permission we may use some of your words from the interviews in the things that we write about the findings from the study. But if we do this, we will not include your name or anything that might mean that people could identify you.

The University of Bristol is the sponsor for this study based in the United Kingdom. The sponsor will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Personal data (e.g. contact details) will be stored for 12 months after the study has ended and then destroyed. Anonymised electronic research data (anonymised electronic transcripts of the audio-recordings) will be stored indefinitely in keeping with the University of Bristol Research Data Repository policy. All data procedures will be in keeping with Medical Research Council (MRC) guidelines, and the General Data Protection Regulation (GDPR) and Data Protection Act 2018.
For more information please visit http://www.highlights.rsc.mrc.ac.uk/GDPR/keep.html.

11. How will we use information about you?

We will need to use information that you provide about yourself for this research project. This information will include your name and contact details. People will use this information to do the research or 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.

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. Once the data has been analysed, we will seek to share our findings through publication, presentation and the media. All reports will be written in a way that ensures that no-one can work out that you took part in the study.

12. 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.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, your data saved from this study may be used for future research by researchers who meet the criteria for access to confidential data, and after the University of Bristol Data Access Committee has approved their request. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you.

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

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

- at http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- by asking one of the research team
- by sending an email to data-protection@bristol.ac.uk , or
- by calling the University's Data Protection Officer on (0117) 3941824.

14. What will happen to the results of the study?

You will be provided with a summary of the findings of this study if you wish to receive it. The results of this study will be published in reports, scientific journals and presented at conferences.

15. How to ask for advice or make a complaint

For general advice on research or to make a complaint please contact the Research Governance Team at the University of Bristol:

Research and Enterprise Development
One Cathedral Square
Bristol, BS1 5DD
Tel: +44 (0)117 42 83065
Email: research-governance@bristol.ac.uk

- If you have concerns about the way you have been approached or treated during the course of this study, you may wish to contact the Patient Advice and Liaison Service (PALS) on:

[enter local PALS details here]

- To make a formal complaint, please contact your local Clinical Commissioning Group advice and complaints team:

Customer Services Team
NHS Bristol, North Somerset and South Gloucestershire CCG
South Plaza, Marlborough Street
Bristol, BS1 3NX
Tel: 0117 900 2655 or 0800 073 0907 (freephone)
Email: bnssg.customerservice@nhs.net

16. Who has reviewed the study?

The study has been reviewed and approved by the National Institute for Health Research Health and Technology Assessment panel, the Bristol, North Somerset & South Gloucestershire NHS Clinical Commissioning Group, and the NHS South West Clinical Research Network. This study received ethical approval by East Midlands - Leicester Central Research Ethics Committee on 20th July 2020 [reference 20/EM/0185] and Health Research Authority approval on 14th August 2020.

17. What happens next?

If you wish to discuss taking part in the study, please call, text or email Dr Andrew Moore, and include the name of your GP practice:

Dr Andrew Moore
Tel: 07969 554827
a.j.moore@bristol.ac.uk

Please respond within the next 7 days if possible, as that will help us to know how many people are interested.

Thank you very much for taking the time to read this information sheet.

Please keep this copy of the information sheet.