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

Clinician Information Sheet

An interview about intra-articular Corticosteroid injections for Osteoarthritis.

1. Invitation

We would like to invite you to take part in an interview about your views and experiences of prescribing/administering intra-articular corticosteroid injections for osteoarthritis, and your motivations for using them or not. Please take some time to read this information sheet carefully before deciding whether you would like to take part in an interview.

2. What is the purpose of the study?

This study is commissioned by the National Institute for Health Research Health Technology and Assessment (HTA) panel. Current evidence for the use of intra-articular corticosteroids for osteoarthritis suggests some short-term benefit on pain relief and mild or no evidence of adverse effects. Given that the prevalence of osteoarthritis is expected to rise over the coming years and concerns that intra-articular corticosteroid injections will be used more frequently in patients, robust evidence on the long-term benefits and risks associated with recurrent use of intra-articular corticosteroid injections for osteoarthritis is urgently needed.

By conducting interviews, we hope to learn more about clinicians' views and experiences of using intra-articular corticosteroids for osteoarthritis and their views about efficacy. We also hope to understand more about factors that affect decision-making on use of intra-articular corticosteroid injections including complications, comorbidities, and perceived risks of repeated use. Additionally, we wish to understand more about clinicians' views of current recommendations for use of intra-articular corticosteroid injections and how they fit into the osteoarthritis care pathway.

3. Why have I been invited?

We have approached you as you are a primary care practitioner with experience of treating patients for osteoarthritis. We would like to talk to up 30 clinicians with different experiences of prescribing/administering intra-articular corticosteroid injections for this purpose, including some clinicians who have not used them.

4. Do I have to take part?

No, it is entirely your decision.

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

- If you would like to take part please contact Dr Andrew Moore, the research fellow conducting the study, by email, text or by telephone, to discuss taking part. The contact details are at the end of this information leaflet.
- If after discussing the study you then agree to participate an interview can be arranged, by telephone or by video call (e.g. Skype) whichever you prefer.
- The interview may take up to 45 minutes. We will be asking the same questions to all clinician participants in the study, and you will also have the chance to tell us about anything that you feel that it would be helpful or important for us to know.
- With your consent, we would like to audio-record the interview. 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.
- Prior to the 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 an electronic eConsent form and you can return this via email.
- Again, with your consent, we may use some anonymised quotations from the interview in any final published results. We would also like to send you a summary of the results if you agree.

6. When and where will the interview take place?

We will aim to either speak with you by telephone or video-call at a time convenient to you, agreed in advance.

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 participate in the interview. Your time will be reimbursed as a service support cost. 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 the study will form part of the evidence base needed to inform the use of intra-articular corticosteroid injections for osteoarthritis, and development of future research.

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 completely or stopped and restarted 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 on research or make a complaint

- For general advice on research 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 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, email or text Dr Andrew Moore:

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

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

Please keep this copy of the information leaflet