NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

University of BRISTOL

Injections for osteoarthritis: questions for future research

The RUBICON-D study (RecUrrent Intra-articular Corticosteroid injections in Osteoarthritis)

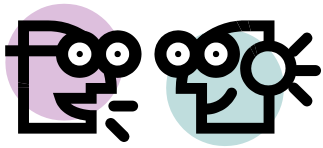
Patient Information Booklet

Helping you decide whether or not to join our research study

We would like to invite you to take part in our research study. Before you decide, it is important for you to understand why the study is being done and what it will involve. Please read the following information to help you to decide whether or not you wish to take part. You may wish to discuss this with family, friends or your healthcare professional.

If there is anything you do not understand, or if you would like further information, please contact Dr Vikki Wylde on 0117 414 7878 or at v.wylde@bristol.ac.uk

Part 1 tells you the purpose of the study and what will happen if you take part.



Part 2 gives you more detailed information about how the study will happen.

Part 1

1. What is the purpose of the study?

- Osteoarthritis is a condition that causes joints to become painful and stiff. Management of osteoarthritis involves reducing pain and maintaining mobility. One treatment that people can be offered is an injection into the affected joint, to try and reduce the pain. These injections are known as ‘cortisone injections’ or ‘steroid injections’. The injection usually contains both an anaesthetic to help with the pain and a steroid to reduce swelling within the joint.
- A lot of research is done to try and improve care for people with osteoarthritis. We are interested in what research should be done on injections for people with osteoarthritis. To help with this, it is

useful to ask people who have had an injection about their views and opinions.

- This study aims to find out what future research on injections for osteoarthritis is needed and the most acceptable way of doing this. In this way, we hope to be able to help researchers and healthcare professionals know which research questions are the most important to patients and other people involved in care delivery.

2. Do I have to take part?

- No. It is up to you to decide whether or not to take part in this study and taking part is voluntary. You do not have to give a reason for deciding not to take part. Your decision will not affect, in any way, the standard of treatment you are receiving or any treatment you may have in the future.

3. Why have I been invited to take part?

- Your GP records identify you as having had a cortisone/steroid injection for osteoarthritis, 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. What will happen to me if I take part?

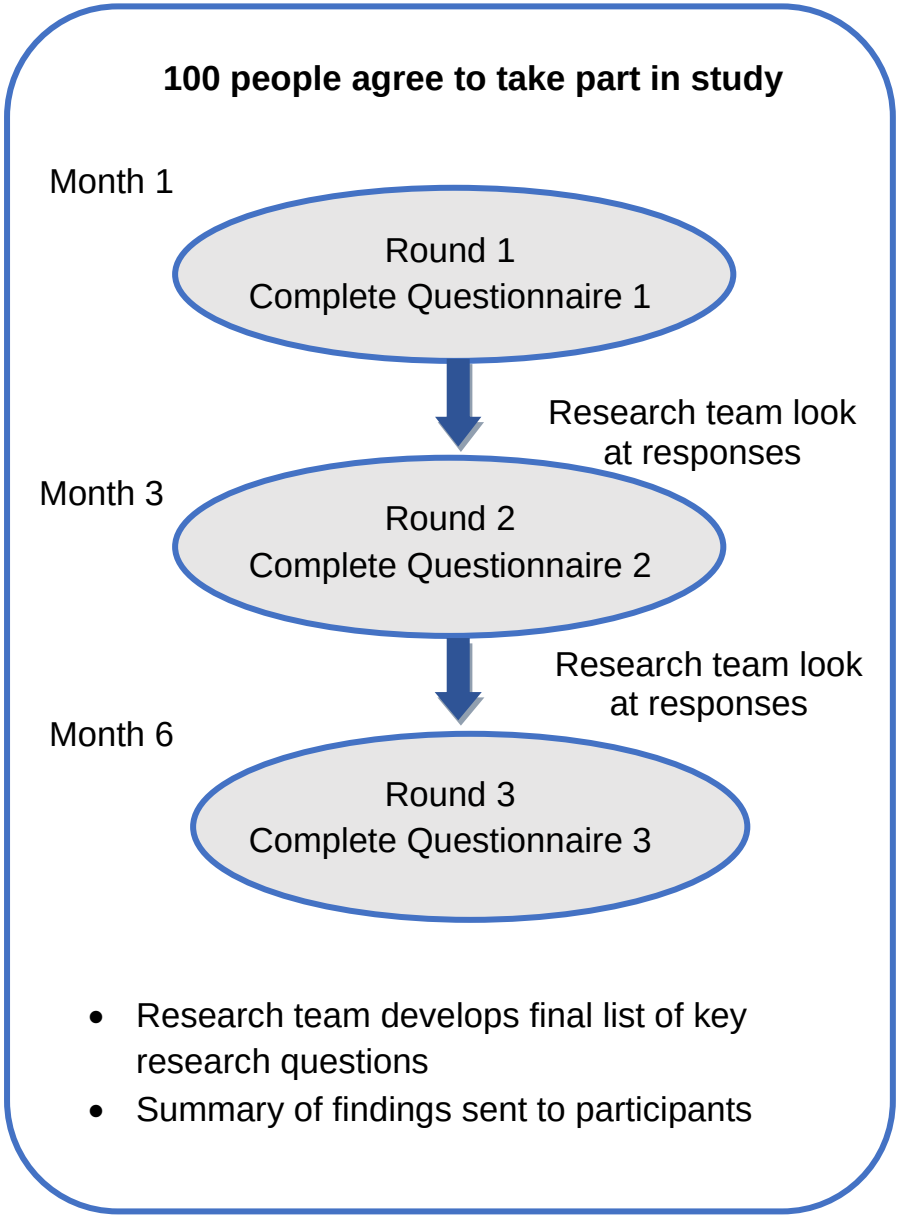
- If you decide you would like to take part in the study after you have read all the information, you will be asked to provide your written agreement to doing so, which we call your ‘consent’. This involves filling in the consent form that is included in the questionnaire booklet.

- You will then be asked to complete 3 questionnaires in total, over a 6-8 month period. We expect that each questionnaire could take up to 30 minutes to complete. The first questionnaire is included with this information booklet. We will involve 100 people, including patients with experience of having an injection for osteoarthritis, healthcare professionals and researchers.

- In the first questionnaire (‘Round 1 questionnaire’), you will be asked to suggest up to five topics for research (further inquiry). This can be based on your experience or aspects of care that you think could be improved. We would like to hear about your own experiences but examples could include how well injections work, recovery after an injection, or

what information is given to patients before having an injection.

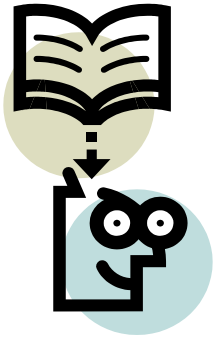
- In the second questionnaire (‘Round 2 questionnaire’), we will send you a list of research questions that people suggested in Round 1. For each research question, we will ask you to rate how important you think the question is from 1-9 (Not important to Very important).
- The final questionnaire (‘Round 3 questionnaire’) will include a shorter list of the research questions that were rated as most important by people in Round 2. You will also be told how the group rated each research question, on average. At this stage you will have the option of keeping your ratings the same or changing them.
- At the end of the study we would also like to send you a summary of the results if you tell us that you would like this.
- If you have any questions about the study, either before deciding to take part or during the study, please contact Dr Vikki Wylde, the researcher conducting the study, by email or by telephone. The contact details are at the end of this information booklet.
- The next page sets out a flow chart of the study.


100 people agree to take part in study
Month 1
Round 1
Complete Questionnaire 1
Research team look at responses
Month 3
Round 2
Complete Questionnaire 2
Research team look at responses
Month 6
Round 3
Complete Questionnaire 3
Research team develops final list of key research questions
Summary of findings sent to participants

5. What are the possible benefits and disadvantages of taking part?

- Although this study will not benefit you directly, we hope that the results of the study will help future research to improve the management of painful osteoarthritis.
- A possible disadvantage is the time it takes you to complete the questionnaires. This may be up to 30 minutes for each questionnaire booklet.

This completes Part 1 of the Information Booklet.
If the information in Part 1 has interested you and you are considering taking part please continue to read the additional information in Part 2 before making any decisions.



Part 2

6. How will you make sure my details are kept confidential?

- All the information you give us (we refer to this as ‘data’) will be kept strictly confidential. The data will be stored in locked filing cabinets and on password-protected computers and will only be accessed by members of the research team. However, if you disclose information that leads us to be concerned about your physical or mental well-being, we may discuss this with an appropriately trained professional outside of the research team.

- The University of Bristol is the sponsor for this study and will be using information from you in order to undertake this study and will act as the data controller. 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 (your questionnaire responses) 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

guidelines, and the General Data Protection Regulation and Data Protection Act 2018. For more information please visit: http://www.highlights.rsc.mrc.ac.uk/GDPR/keep.html

7. How will we use information about you?

- We will need to use information that you provide about yourself for this study. 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 media. All reports will be written in a way that ensures no-one can work out that you took part in the study.

8. 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 in 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.

9. 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
- By calling the University's Data Protection Officer on 0117 3941824

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

- You will be provided with a brief 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.

11. Who is organising and funding this study?

- The study is being carried out by researchers from the University of Bristol. The study is sponsored by the University of Bristol and funded by a grant from the National Institute for Health Research, which is funded by the Department of Health (reference NIHR129011). More details about the funding are provided at: https://fundingawards.nihr.ac.uk/award/NIHR129011

12. 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 at research-governance@bristol.ac.uk or on 0117 42 83065

- To make a formal complaint, please contact your local Clinical Commissioning Group advice and complaints team on 0117 900 2655 or 0800 073 0907 (freephone) or at bnssg.customerservice@nhs.net

13. Who has reviewed the study?

- This study has been given a favourable opinion for conduct in the NHS by the National Research Ethics Service Committee (Proportionate Review Sub-Committee of the North of Scotland Research Ethics Committee) and the Health Research Authority.

14. What happens next?

- If you wish to take part in the study, please complete the questionnaire and consent form and return them to us in the pre-paid (no stamp required) envelope provided. We will then send you the Round 2 questionnaire in 2-3 months' time. If you have any questions about the study, please contact:

Dr Vikki Wylde

Tel: 0117414 7878

v.wylde@bristol.ac.uk

We would be grateful if you could 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 leaflet.

Please keep this copy of the information leaflet.

Some members of the research team

Vikki Wylde

Mike Whitehouse

Andrew Judge

Andrew Moore

FUNDED BY
NIHR | National Institute for Health Research