NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

University of BRISTOL

Injections for osteoarthritis: questions for future research

The RUBICON-D study

Professionals' Information Booklet

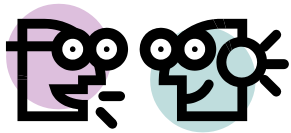
Helping you decide whether or not to join our research study

We would like to invite you to take part in our research study. Before you decide to take part, it is important for you to understand why the research 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.

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

Professional information booklet for secondary care clinicians, Commissioners and academics • Version 1 • 01.04.2021 • IRAS 284918

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 project 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 function. One treatment that people can be offered is an intra-articular corticosteroid injection into the affected joint, to try and reduce the pain. The injection usually contains both an anaesthetic to help with the pain and a steroid to reduce swelling within the joint.
- We are interested in what research should be done on injections for people with osteoarthritis, so that we can develop recommendations for future research priorities. To do this, we are asking patients and experts with relevant experience about their views and opinions so that

we can reach consensus on recommendations future research priorities.

- By doing this, we hope to be able to help researchers and healthcare professionals know which research questions are the most important to patients, healthcare professionals, academics and those involved in the planning of musculoskeletal services.

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?

- We are approaching you about the study because you have experience of either treating patients with osteoarthritis, conducting research into treatments for osteoarthritis or working in the planning of musculoskeletal services

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 about the study, you will be asked to provide your written consent. This involves filling in the consent

form that can be accessed via an online link (detailed provided below).

- You will then be asked to complete 3 questionnaires over a 6-8 month period. This type of survey is called a Delphi study.

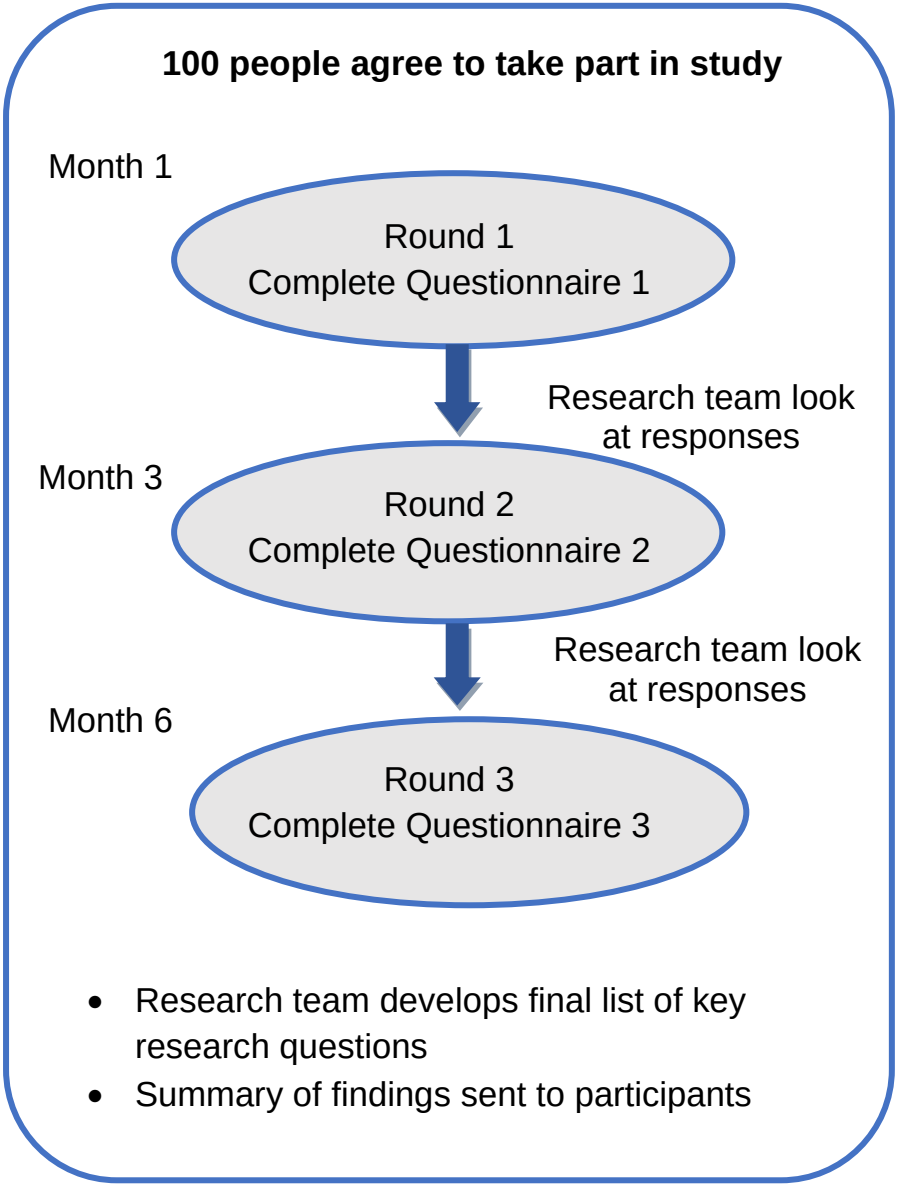
- We expect that each questionnaire could take up to 30 minutes to complete. The first questionnaire can be accessed via this link: https://meded.onlinesurveys.ac.uk/rubion-d-round-1
- We will be asking 100 people to take part, including patients with experience of having an injection for osteoarthritis, healthcare professionals, academics and people involved in the planning of musculoskeletal services.

- In the first questionnaire ('Round 1 questionnaire'), you will be asked to suggest up to five topics for research. This can be based on your own experience or aspects of care that you think could be improved.

- 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 rating the same or changing them.

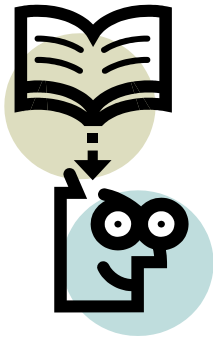
- At the end of the study we would also like to send you a summary of the results if you tell us that you would like this.
- If you have any questions about the study, either before deciding to take part or during the study, please contact Dr Vikki Wylde, the researcher conducting the study, by email or by telephone. The contact details are at the end of this information booklet.


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 inform future research to improve care for people with 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 data you give us 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.

- The University of Bristol is the sponsor for this study. 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 (your responses to the questionnaires) 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

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 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.

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). Further details of the funding are provided at: http://fundingawards.nihr.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

- If you have concerns about the way you have been approached or treated during the course of this study, you may wish to 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?

- The study has received ethics approval from the Proportionate Review Sub-Committee of the North of Scotland Research Ethics Committee Research Ethics Committee (reference 21/NS/0070) and Health Research Authority approval.

14. What happens next?

- If you wish to take part in the study, please complete the questionnaire and consent form by clinking on this link: https://meded.onlinesurveys.ac.uk/rubion-d-round-1
- 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

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

Vikki Wylde

Mike Whitehouse

Andrew Judge

Andrew Moore

FUNDED BY

NIHR | National Institute for Health Research