Methotrexate Oral Or SubcutanEous for RA

Treatment acceptability

The **MOOSE** Study

Participant Information Sheet

1. You are invited to take part in our research study

- The MOOSE study is looking at whether methotrexate injections are more effective than methotrexate tablets in treating rheumatoid arthritis and improving wellbeing in newly diagnosed patients.
- As part of the study, we would like to hear your experience of your treatment and how satisfied you have been whilst taking your allocated treatment.
- This information sheet is to help you understand why the treatment acceptability discussion is being carried out and what it will involve for you if you decide to take part
- Please take time to read this information and ask us if there is anything that is not clear to you, or you would like more information
- It is entirely your decision whether to take part in the one to one discussion. If you agree to take part, you are free to withdraw from this part of the MOOSE study at any time without giving a reason. If you choose not to take part, it will not impact your participation in the main study or your care.

2. Study summary and purpose of the treatment discussions

A few research studies have suggested that methotrexate injections might be better at treating RA and cause fewer side effects than tablets, but not enough research has been done for us to know for sure. We are conducting this part of the study to find out patients views on treatment with methotrexate tablets or injections.

3. Why have I been invited to take part?

When you completed your consent form for the MOOSE study, you agreed to be contacted about this part of the study about treatment acceptability. We are inviting a small number of people in the MOOSE study to talk about their experiences with a researcher.

4. Do I have to take part?

It is up to you whether you take part in this part of the study. You can contact the researcher (details in section 15) to talk about what will happen and answer any questions you may have. If you agree to take part, we will ask you to complete a consent form.

5. What would taking part involve?

If invited, the first discussion will take place around the same time as your 4 week clinic visit. You will be asked about your understanding and thoughts on your arthritis diagnosis and the methotrexate treatment you are using. We will speak to you again at the end of the study to find out about your experiences with your treatment whilst in the study for example if things have changed over time and why. These discussions will take place over the phone or over video call (depending on what you prefer). You do not need to be in the hospital for this discussion and we will talk to you by phone or video call while you are at your home.

When we talk to you, we would like to know about how you have found taking/using the treatment and whether you would be likely to choose that treatment again in the future. Discussions will take around one hour and will be audio or video recorded. These will be individual discussions that will only involve you and the researcher. A professional transcription company will make a written copy of the discussion. They operate under strict terms of confidentiality, and only members of the research team will see the data. No other patients, participants or your clinical care team will know what you have said during the discussion.

6. What are the possible benefits of taking part?

Taking part in the discussion is unlikely to benefit you directly, but the information you provide will help us better understand methotrexate treatment and may help us improve treatment for people with RA in the future.

7. What are the possible disadvantages and risks of taking part?

We do not anticipate that there are any risks involved in participating in this study. If, during the interview, a question brings back unhappy memories or distressing thoughts that you do not wish to discuss, then the researcher will not pursue the topic any further from that point on in the interview. If we have concerns that you or someone else is at risk of harm, then we may have to inform relevant healthcare services, for example your rheumatology team. If you would like to speak to somebody about your arthritis after answering these questions you could contact your GP or your rheumatologist. We can also provide details of support groups, helplines or counselling service such as 'Improving Access to Psychological Support' (IAPT) services. Alternatively, if you would like to speak to somebody about the study you can call the study coordinating centre (details in section 9).

8. What if there is a problem?

If you have concerns or questions about any aspect of this study, you should ask to speak to the researcher. Their contact details are at the end of this information sheet.
If any questions remain you can contact the study coordinating centre:
Tel: 0115 823 1604, contactable Monday to Friday: 9:00 – 16:00
Email: moose@nottingham.ac.uk

If you have any questions or concerns about taking part in research you can contact NHS England on Tel: 0300 311 2233, email: england.contactus@nhs.net

9. What will happen if I don't want to carry on with the treatment discussions?

You are free to withdraw at any time, without giving any reason, from the treatment discussions. This will not affect your involvement in the main study. If you withdraw from either the main study or the treatment discussions, your legal rights will not be affected. If you withdraw, we will no longer collect any information about you or from you, but the information already collected will not be erased and this information may still be used in the project analysis.

10.How will information about me be used?

Researchers from the University of Keele will have access to your name and contact details for the purpose of contacting you about this research.

Audio or Video-recordings of the discussions you have will be typed out to make a paper copy of the discussion (called a transcript). This will be carried out by a professional transcription company who operate under strict terms of confidentiality. The transcript will then be pseudonymised. This means that your name will not be used in any of the transcripts. If direct quotations from the audio or video recording are included in future reports and publications, these will also be pseudonymised. Both the audio/video recording and the paper transcripts of interviews will be stored securely, and the pseudonymous transcript may be re-used by researchers in the future.

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. This information will be kept **strictly confidential**, stored in a secure and locked office within the University of Keele, and on a password protected database at the University of Nottingham. Our procedures for handling, processing, storage of and destruction of data are in line with relevant regulatory requirements.

In accordance with Sponsor, Government and funder policies we may share anonymised research data with researchers in other Universities and organisations, including those in other countries. Sharing research data is important to understand the bigger picture in particular areas of research.

Once the study has finished, the data will be kept for a minimum of 10 years. The results will be checked and you will be told what happened in the study (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that you took part in the study.

11.What are your choices about how your information is used?

You can stop being part of the treatment discussions 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. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

After 10 years your data collected during the study will be disposed of securely. If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research to do with your RA that you may be interested in taking part in.

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

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

- at **www.hra.nhs.uk/information-about-patients/** and **www.hra.nhs.uk/patientdataandresearch**
- at https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx and http://www.nctu.ac.uk/data-protection/data-protection.aspx
- by asking one of the research team
- by sending an email to moose@nottingham.ac.uk
- by calling the Nottingham Clinical Trials Unit on 0115 823 1604

13.Who is organising and funding this study? How has it been approved?

The study is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the trial is provided by the National Institute of Health Research Health Technology Assessment (NIHR HTA 13271). Professor Abhishek, Professor of Rheumatology is the Chief Investigator of this study. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by a **<enter specific committee here>** Research Ethics Committee.

Patients who have previously been treated for rheumatoid arthritis and have been treated with methotrexate have helped us plan and design this study. Patients' representatives are also involved in the teams that oversee the running of the study and a Patient Advisory Group has worked with us to create the patient documentation.

14.How to contact us

Contact details of the researcher;

- <insert contact details here, Keele team>