

Does an information booklet about Rheumatoid Arthritis and Methotrexate, help patients manage their Arthritis better?

Submission date 25/03/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to explore the effect of a Rheumatoid Arthritis (RA) Information booklet on the disease management of patients with RA who are taking Methotrexate. Methotrexate is the default disease modifying drug (DMARD) for treatment of RA. It is a drug; which has a delayed onset of action and where the majority of patients, even those continuing on treatment, have side effects that they tolerate in order to stay on the drug. Poor disease management in the form of not taking Methotrexate as prescribed can give the impression that the therapy has failed which could have an economic impact on the NHS. Chugai/Roche produced a booklet for people who have Rheumatoid Arthritis. This has been designed to prompt the patients to think about and assess how their treatment suits them.

Who can participate?

Anyone over 18 years of age who has been taking methotrexate at a stable dose for 3 months can take part in this study.

What does the study involve?

All you have to do to take part in this study, is to sign a consent form to allow us to give you 2 questionnaires to complete, then take approximately 10 mls of blood during your routine blood monitoring visit. You will not need any extra needles in your arm. We will randomise you to receiving the Roche Information Booklet or the Arthritis Research UK information leaflet. Then, when you return in 3 – 6 months to repeat your blood monitoring we will ask you to complete the questionnaires again and we will take 10 mls of blood during your blood monitoring so that you don't need an extra needle in your arm. This whole process should not take more than an extra 10 minutes to your regular appointment on each occasion. That would complete your participation in the study. However, if you would like to know the results, please leave your details with the study team and we will post or email our results to you.

What are the possible benefits and risks of participating?

You would have the opportunity to learn more about your condition and the medication you take. We will give you the Roche education booklet when you return for your second visit. We

hope that this information will empower you to ask more questions when you see your doctor or nurse and help you to manage your arthritis better. Also, discovery through research studies like this could lead to benefits in the future for people like yourselves who have similar conditions. There are no particular risks of taking part in this study as we do not intend to take blood samples from you unless you are having this done as part of your normal routine care. Your blood samples will be analysed at the University of Newcastle Upon Tyne. However there is no risk of any identifiable data being released as all of the samples will be anonymised and only your unique study number will identify them. Newcastle University would like to keep any unused samples for further research, but these would also be completely anonymised.

Where is the study run from?

North Tyneside General Hospital, UK

When is the study starting and how long is it expected to run for?

March 2019 to February 2021 (updated 05/08/2020, previously: September 2020)

Who is funding the study?

Chugai Pharma Europe Ltd. and the National Institute for Health Research

Who is the main contact?

Sandra Robinson, sandra.robinson3@nhct.nhs.uk

Contact information

Type(s)

Public

Contact name

Dr Sandra Robinson

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

189766

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

37811, IRAS 189766

Study information

Scientific Title

Adherence to Methotrexate in Rheumatoid Arthritis: Effect of an Information Booklet on Methotrexate Levels

Study objectives

Education with the rheumatoid arthritis information booklet leads to improved methotrexate adherence

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/10/2018, South West – Central Bristol Research Ethics Committee (Whitefriars Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT; nrescommittee.southwest-bristol@nhs.net; 0207 104 8028), ref:18/SW/0191

Study design

Interventional randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Subjects will be randomised 50:50 to receive the Rheumatoid Arthritis information booklet. Those participants who do not receive the booklet at randomisation will receive it 3 – 6 months later when the participant returns for their routine Methotrexate blood monitoring

appointment. The aim of this is to determine whether the intervention of the Rheumatoid Arthritis information booklet has an impact on patient Methotrexate management. All patients will be given the Methotrexate Adherence questionnaire and the RA Questionnaire at screening and again 3 – 6 months later.

A Simple Randomisation Process will be used with an online randomisation tool: Sealed Envelope Ltd 2016

Two study arms, 50% of patients receive an Information Booklet on Rheumatoid Arthritis and Methotrexate and 50% do not receive the booklet at the first meeting. Both groups will be given a Rheumatoid Arthritis Knowledge Questionnaire and a methotrexate Adherence Questionnaire at the first meeting. Both groups will also have their methotrexate levels measured by a blood test at this first meeting. All participants will be followed up 3 – 4 months later, all participants will be asked to repeat the questionnaires and Methotrexate levels will be measure in a blood sample for all patients.

Intervention Type

Other

Primary outcome measure

1. Knowledge of RA measured using the Multiple Choice Rheumatoid Arthritis Questionnaire at the first meeting and the follow up meeting 3 – 4 months later
2. Methotrexate Adherence is measured using Visual Analogue Scales on the Methotrexate Adherence Questionnaire at the first meeting and the follow up meeting 3 – 4 months later.

Secondary outcome measures

Methotrexate levels measured from a blood sample taken from all participants at the first meeting and 3 – 4 months later at the second meeting.

Overall study start date

13/03/2019

Completion date

01/01/2021

Eligibility

Key inclusion criteria

1. Subjects capable of giving informed consent in English
2. Male or female
3. Over the age of 18 years
4. Diagnosis of Rheumatoid Arthritis
5. On a stable dose of Methotrexate for at least 3 months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment

73

Key exclusion criteria

1. Unwilling or unable to take Methotrexate
2. Unwilling or unable to return for their Methotrexate blood monitoring 3 – 6 months later
3. Unable to read the questionnaires or the Rheumatoid Arthritis booklet
4. Unable to read English

Date of first enrolment

18/03/2019

Date of final enrolment

01/01/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

North Tyneside General Hospital

Rake lane

North Shields

United Kingdom

NE29 8NH

Sponsor information

Organisation

Northumbria healthcare NHS foundation trust

Sponsor details

Rake Lane

North Shields

England
United Kingdom
NE29 8NH
0191 2934087
Peta.heslop@nhct.nhs.uk

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/01gfeyd95>

Funder(s)

Funder type

Industry

Funder Name

Chugai Pharma Europe Ltd.

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The study team plan to present the results of the study at the British Society of Rheumatology Annual Meeting, the study team also plan to publish the results in a peer reviewed journal of Rheumatology.

Intention to publish date

01/04/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		20/08/2018	08/04/2019	No	No
Basic results			10/05/2023	No	No
HRA research summary			28/06/2023	No	No