ISRCTN14741429 https://doi.org/10.1186/ISRCTN14741429

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

Registration date
08/04/2019

Overall study status
Completed

Last Edited
10/05/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
189766

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Methotrexate levels measured from a blood sample taken from all participants at the first meeting and 3 – 4 months later at the second meeting.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
North Tyneside General Hospital
Rake lane
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation
Northumbria healthcare NHS foundation trust

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

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?
Basic results			10/05/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file		20/08/2018	08/04/2019	No	No