Self monitoring of methotrexate by patients with arthritis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
18/11/2010		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
29/06/2011		[X] Results		
Last Edited 03/08/2020	Condition category Musculoskeletal Diseases	[] Individual participant data		
03/00/2020	ויוטפנטנטפובנפנטנטופפפפפפ			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Self monitoring of treatment with methotrexate alone or in combination with anti-tumour necrosis factor alpha by patients with arthritis: a randomised controlled trial

Study objectives

Teaching patients with arthritis how to interpret their own blood test results and appropriately initiate outpatient appointments will lead to changes in patient awareness of the role they play in their own condition compared to usual care

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West London Research Ethics Committee 1, 23/12/2009, ref: 09/H0722/91

Study design

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 and psoriatic arthritis

Interventions

- 1. Demorgaphics (age, gender, living status, ethnicity) and clinical data (date of diagnosis, methotrexate start date, number of previous disease modifying anti-rheumatic drugs) will be collected at baseline
- 2. Participants will be randomised to one of two groups:
- 2.1. Intervention group:
- 2.1.1. The 2 hour self-monitoring training session will present the rationale of self-monitoring, an overview of the blood tests, physical symptoms and side-effects requiring monitoring for people taking methotrexate and a self-injected anti-TNF agent, training in how to identify normal or 'safe' ranges of blood levels, side effects and symptoms and decide, if any action is necessary
- 2.1.2. Intervention participants will monitor 6 consecutive blood tests which include markers of

inflammation - C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), plus haemoglobin (Hb), white cell count (WCC) and liver function tests (ALP and ALT)

- 2.1.3. The first 3 blood tests will be monitored in collaboration with a member of the research team and the subsequent 3 independently
- 2.1.4. The information obtained will be used to initiate outpatient's appointments with a Rheumatology Nurse Specialist
- 2.2. Control group usual care

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Methotrexate

Primary outcome measure

The self management role and responsibility subscale of the Medication Education Impact Questionnaire, measured at baseline and again after the 3rd and 6th blood tests.

Secondary outcome measures

- 1. Impact of Methotrexate assessed by Medication Impact Questionnaire at baseline and after 3rd and 6th blood test
- 2. Knowledge about Methotrexate assessed by Methotrexate in Rheumatoid Arthritis Knowledge at baseline and after 3rd and 6th blood test
- 3. Impact of arthritis assessed by Health Education Impact Questionnaire at baseline and after 3rd and 6th blood test
- 4. Mood, anxiety and depression assessed by Hospital Anxiety and Depression Scale (HADS) at baseline and after 3rd and 6th blood test
- 5. Beliefs about arthritis assessed by Illness Perceptions Questionnaire Revised at baseline and after 3rd and 6th blood test
- 6. Social support at baseline and after 3rd and 6th blood test
- 7. Generalised Self Efficacy at baseline and after 3rd and 6th blood test
- 8. Beliefs about Methotrexate assessed by Beliefs about Medication Questionnaire at baseline and after 3rd and 6th blood test
- 9. Healthcare utilisation assessed by Treatment Burden (1-item measure) at baseline and after 3rd and 6th blood test
- 10. Self-reported adherence to Methotrexate Medication Adherence Report Scale at baseline and after 3rd and 6th blood test
- 11. Functional disability assessed by Health Assessment Questionnaire-II at baseline and after 3rd and 6th blood test
- 12. Pain in last 2 weeks assessed by Pain Visual Analogue Scale (VAS) (0-10) at baseline and after 3rd and 6th blood test
- 13. Fatigue in last 2 weeks assessed by Fatigue VAS (0-10) at baseline and after 3rd and 6th blood test
- 14. Disease activity (RA & PsA) assessed by Disease Acitivity Score in Rheumatoid Arthirtis-28 & Psoriatic Arthritis Response Criteria at baseline and after 6th blood test

Overall study start date

01/02/2010

Completion date

01/06/2012

Eligibility

Key inclusion criteria

- 1. All patients with a diagnosis of Rheumatoid or Psoriatic arthritis
- 2. Aged 18 years or over
- 3. Fluency in written and spoken English
- 4. Patients whose treatment is classified as stable defined as those who have had disease management with methotrexate for at least 6 months, plus a further 6 months if the patient is receiving a self-injected anti-TNF agent (Adaliumab or Etanercept)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

- 1. Identifiable psychosis or dementia
- 2. Significant co-morbidity (i.e. their predominant treatment is for another illness)
- 3. Those whose blood tests are being monitored by their GP

Date of first enrolment

01/02/2010

Date of final enrolment

01/06/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

City University London

London United Kingdom EC1V 4PB

Sponsor information

Organisation

Joint UCLH and UCL Biomedical Research Unit (United Kingdom)

Sponsor details

Ground Floor Rosenheim Wing 25 Grafton Way London United Kingdom WC1E 5DB

Sponsor type

Not defined

Website

http://www.ucl.ac.uk/joint-rd-unit/

ROR

https://ror.org/03r9qc142

Funder(s)

Funder type

University/education

Funder Name

University College London Hospitals Charity (United Kingdom)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No
Results article	cost-effectiveness results	05/01/2021	03/08/2020	Yes	No