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Self monitoring of methotrexate by patients with arthritis

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
Joint UCLH and UCL Biomedical Research Unit (United Kingdom)

Sponsor details
Ground Floor
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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 summary

Not 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