

# Self monitoring of methotrexate by patients with arthritis

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| <b>Submission date</b><br>18/11/2010   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>29/06/2011 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>03/08/2020       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Rheumatoid and psoriatic arthritis

### **Interventions**

1. Demographics (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(s)**

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.

**Key secondary outcome(s)**

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 Activity Score in Rheumatoid Arthritis-28 & Psoriatic Arthritis Response Criteria at baseline and after 6th blood test

**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 (Adalimumab or Etanercept)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

City University London

London

United Kingdom

EC1V 4PB

**Sponsor information****Organisation**

Joint UCLH and UCL Biomedical Research Unit (United Kingdom)

**ROR**

<https://ror.org/03r9qc142>

# Funder(s)

## Funder type

University/education

## Funder Name

University College London Hospitals Charity (United Kingdom)

# Results and Publications

## 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? |
|---------------------------------|----------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results                    | 01/07/2016   |            | Yes            | No              |
| <a href="#">Results article</a> | cost-effectiveness results | 05/01/2021   | 03/08/2020 | Yes            | No              |