

# A pilot study assessing the clinical effectiveness of dipyridamole in patients with active disease on methotrexate for rheumatoid arthritis with imaging analysis

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 05/07/2016	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## 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**

N0436146603

## **Study information**

### **Scientific Title**

A pilot study assessing the clinical effectiveness of dipyridamole in patients with active disease on methotrexate for rheumatoid arthritis with imaging analysis

### **Study objectives**

Methotrexate (MTX) has been commonly used in the treatment of rheumatoid arthritis (RA) for more than 20 years, and is safe and well tolerated. Although weekly low dose MTX is now first-line therapy because of its efficacy and safety, some patients still do not respond enough or cannot tolerate taking the sufficient dose of MTX because of its side effects. Since recently available biological therapy such as anti-tumour necrosis factor (TNF) agents are not only effective, but also expensive (approx annual cost of £9,000/year) this treatment is only available for the patients with long standing resistant disease. It would be still desirable to find an approach which can reduce or suspend the needs of the biologics. A series of studies have shown that adenosine is released in high concentrations from cells and tissues after treatment with MTX.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **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 contact details to request a participant information sheet

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

Rheumatoid arthritis

**Interventions**

Randomised controlled trial

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Dipyridamole, methotrexate

**Primary outcome measure**

Clinical efficacy of dipyridamole combined with MTX at 8 weeks, as measured by DAS28 score with EULAR response

**Secondary outcome measures**

1. Number of patients requiring additional anti-rheumatic therapy
2. Change in the following individual clinical, laboratory and quality of life outcome measurements:
  - 2.1. C-reactive protein (CRP)
  - 2.2. Health Assessment Questionnaire (HAQ)
  - 2.3. Visual Analogue Scale (VAS)
  - 2.4. Early morning stiffness/tender and swollen joint count (66/68) ratio

**Overall study start date**

01/01/2004

**Completion date**

01/03/2004

**Eligibility****Key inclusion criteria**

Patients attending general Rheumatology clinics will be invited to participate

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

20

**Key exclusion criteria**

1. Pregnant or nursing women
2. Concomitant serious medical conditions presently severe, progressive or uncontrolled
3. Contraindication to proposed therapeutic agents
4. Taking theophylline and/or treated for asthma

**Date of first enrolment**

01/01/2004

**Date of final enrolment**

01/03/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Leeds General Infirmary**

Leeds

United Kingdom

LS1 3EX

## Sponsor information

**Organisation**

Department of Health

**Sponsor details**

Richmond House

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London

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

# Funder(s)

## Funder type

Government

## Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

# 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