

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

Submission date 30/09/2005	Recruitment status Stopped	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 05/07/2016	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ 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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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

01/03/2004

Eligibility

Key inclusion criteria

Patients attending general Rheumatology clinics will be invited to participate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration