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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

Registration date
30/09/2005

Overall study status
Stopped

Last Edited
05/07/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
Prof P Emery

Contact details
Rheumatology and Rehabilitation Research Unit
Old Nurses Home
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 392 3995
p.emery@leeds.ac.uk

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 being 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes