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Randomised double blind trial of safety of anti-tumour necrosis factor (anti-TNF) chimeric monoclonal antibody (infliximab) in combination with methatrexate compared to methatrexate alone in patients with rheumatoid arthritis on standard disease modifying anti-rheumatic drugs

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/02/2018	**Condition category** Musculoskeletal Diseases	

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

N0059111730

Study information

Scientific Title
Randomised double blind trial of safety of anti-tumour necrosis factor (anti-TNF) chimeric monoclonal antibody (infliximab) in combination with methatrexate compared to methatrexate alone in patients with rheumatoid arthritis on standard disease modifying anti-rheumatic drugs

Study objectives
Randomised double blind trial of safety of anti-tumour necrosis factor (TNF) chimeric monoclonal antibody (infliximab) in combination with methatrexate compared to methatrexate alone in patients with rheumatoid arthritis on standard disease modifying anti-rheumatic drugs

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
Musculoskeletal Diseases: Rheumatoid arthritis (RA)

Interventions
Infliximab in combination with methatrexate compared to methatrexate alone.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Anti-tumour necrosis factor (TNF), chimeric monoclonal antibody (infliximab), methatrexate

Primary outcome(s)
Currently unavailable

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/09/2003

Eligibility

Key inclusion criteria
Patients with rheumatoid arthritis on standard disease modifying anti-rheumatic drugs (DMARD)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/12/2001

Date of final enrolment
01/09/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Teaching Hospitals NHS Trust
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration