

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/02/2018	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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