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Differentiating the mechanism of action of anti-TNF alpha agents

Submission date	Recruitment status	[ ] Prospectively registered
22/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/01/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2016	Musculoskeletal Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/S0703/64

Study information

Scientific Title
Differentiating the mechanism of action of anti-TNF alpha agents

Acronym
DATA study

Study objectives
Effect of two different anti-TNF inhibitors on mRNA and cytokine protein expression in rheumatoid arthritis and psoriatic arthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Glasgow Ethics Committee 1, 03/10/2006, ref: 06/S0703/74

Study design
Randomised comparative parallel study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Comparing two different anti TNF drugs:
1. Infliximab 3 mg/kg at week 0, 2, 6 and thereafter every 8 weeks administered intravenously for 12 months
2. Etanercept 25 mg twice weekly administered subcutaneously for 12 months

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Effect of the two different anti-TNF inhibitors on mRNA and cytokine protein expression in rheumatoid arthritis and psoriatic arthritis:
1. mRNA, measured at week 0, 4, and 12
2. Cytokines, measured at week 0, 4, and 12

Secondary outcome measures
Effect on clinical and physiological measures and their correlation with changes in mRNA and cytokine expression. The clinical and physiological measures include the following:
1. Synovial biopsy at baseline (week 0) and week 4
2. Skin biopsy at baseline (week 0) and week 4
3. Ultrasound at baseline and 1 month
4. Hypoxia measurements at baseline and 1 month
5. Blood tests:
5.1. Erythrocyte Sedimentation Rate (ESR), measured monthly for the duration of the study (1 year)
5.2. C-Reactive Protein (CRP), measured monthly for the duration of the study (1 year)
5.3. Anti-Cyclic Citrullinated Peptide (anti-CCP) antibody at screening visit
5.4. Rheumatoid factor at screening visit
5.5. Full Blood Count (FBC), measured monthly for the duration of the study (1 year)
5.6. Urea and Electrolytes (U&E's), measured monthly for the duration of the study (1 year)
5.7. Liver Function Tests (LFT's), measured monthly for the duration of the study (1 year)
5.8. Hepatitis B and C at screening visit

Overall study start date
19/03/2007

Completion date
19/03/2009

Eligibility

Key inclusion criteria
Adults with established active rheumatoid or psoriatic arthritis.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria

Prinicipal exclusion criteria in accord with clinical use of anti-TNF inhibitors.

Date of first enrolment
19/03/2007

Date of final enrolment
19/03/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Centre for Rheumatic Diseases
Glasgow
United Kingdom
G31 2ER

Sponsor information

Organisation
NHS Greater Glasgow and Clyde/University of Glasgow (UK)

Sponsor details
Centre for Rheumatic Diseases
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Sponsor type
Government

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
NHS Greater Glasgow and Clyde R&D (ref: RN06RH005) (UK)

Funder Name
University of Glasgow (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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