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

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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 vear)
- 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

Completion date

19/03/2009

Eligibility

Key inclusion criteria

Adults with established active rheumatoid or psoriatic arthritis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Scotland

Study participating centre

Centre for Rheumatic Diseases

Glasgow United Kingdom G31 2ER

Sponsor information

Organisation

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

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

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 11/11/2025 No Yes