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

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

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 University Tower Level 3 Queen Elizabeth Building Glasgow Royal Infirmary 10 Alexandra Parade Glasgow United Kingdom G31 2ER

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