ISRCTN29665463 https://doi.org/10.1186/ISRCTN29665463

A placebo-controlled trial of anti-TNFa chimeric monoclonal antibody (infliximab, remicade) in the modification of vascular disease markers in active rheumatoid arthritis

Submission date
05/03/2007

Recruitment status
No longer recruiting

Registration date
23/11/2007

Overall study status
Completed

Last Edited
14/06/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
RJI 03/0139

Study information

Scientific Title

Acronym
DIVERT - Defining Infliximab Vascular Effects Rheumatoid arthritis Trial

Study objectives
That surrogate measures of vascular disease (pulse wave velocity, flow mediated dilatation, carotid-intimal media thickness), will improve after infliximab therapy in patients with active rheumatoid arthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guy's Hospital Research Ethics Committee, approved on 28 November 2003 (ref: RJI - 03/0139)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Placebo controlled 2:1 randomisation, active infliximab (3 mg/kg intravenous) vs placebo infusion for 26 weeks, then open label until week 56, with placebo escape arm at week 14.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
infliximab

Primary outcome(s)
The following will be assessed at baseline (Week 0), Week 24 and Week 56, unless indicated otherwise:
1. Endothelial function (Flow Mediated Dilatation [FMD]). This will be assessed at Week 8 and Week 16 in addition to the timepoints stated above.
2. Vascular structure:

2.1. Pulse Wave Velocity [PWV]
2.2. Augmentation Index [Aix]
2.3. Carotid Intimal Medial Thickening [CIMT]

Key secondary outcome(s))
The following will be assessed at baseline (Week 0), Week 24 and Week 56, unless indicated otherwise:
1. RA disease activity:
1.1. Modified Health Assessment Questionnaire (HAQ). This will be assessed at Week 8 and Week 16 in addition to the timepoints stated above.
1.2. 28 swollen and tender joint counts. This will be assessed at Week 8 and Week 16 in addition to the timepoints stated above.
1.3. Erythrocyte Sedimentation Rate (ESR)
1.4. Patient Global Assessment (PGA) using a 100 mm visual 1.5. Analogue scale and Disease Activity Score 28 (DAS 28). This will be assessed at Week 8 and Week 16 in addition to the timepoints stated above.

2. CV risk factors:
2.1. Systolic and diastolic Blood Pressure (BP)
2.2. Body Mass Index (BMI)
2.3. High sensitivity C-Reactive Protein (HsCRP)
2.4. Serum fasting lipid profile (total cholesterol, High and Low Density Lipoprotein fractions [HDL, LDL] and triglycerides)
2.5. Oxidised LDL sub-fractions
2.6. Insulin resistance measured by log homeostasis model assessment (HOMA)
2.7. Serum levels of soluble Intracellular Adhesion Molecules (ICAM)
2.8. Vascular Cell Adhesion Molecules (VCAM) and adiponectin

Completion date
15/05/2005

Eligibility

Key inclusion criteria
1. RA defined by American College of Rheumatology criteria
2. Referred for TNF-blocking therapy according to the British Society of Rheumatology (BSR) criteria
3. Patients giving written informed consent
4. Patients failed two DMARDs including methotrexate
5. Disease Activity Score 28 (DAS 28) greater than 5.1 on two occasions four weeks apart
6. Patients taking methotrexate (<=25 mg/week)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age <18 years
2. History of ischemic heart disease, cerebrovascular disease, peripheral vascular disease, diabetes mellitus
3. Previous treatment with infliximab or any therapeutic agent targeted at reducing TNFa
4. Treatment with aspirin
5. Patients with evidence of current or previous infection with tuberculosis (TB)

Date of first enrolment
15/05/2003

Date of final enrolment
15/05/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Rheumatology Department
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's & St Thomas' NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Centocor BV (The Netherlands)

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?
Results article	results	01/08/2009		Yes	No