

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

<b>Submission date</b> 05/03/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/11/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/06/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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]

**Secondary outcome measures**

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 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

**Overall study start date**

15/05/2003

**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 ( $\leq 25$  mg/week)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**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**

England

United Kingdom

**Study participating centre**

Rheumatology Department

London

United Kingdom

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**Sponsor information**

**Organisation**

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

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.guysandstthomas.nhs.uk/>

**ROR**

<https://ror.org/00j161312>

**Funder(s)****Funder type**

Industry

**Funder Name**

Centocor BV (The Netherlands)

**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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2009		Yes	No