

A randomised controlled trial of Infliximab in ANCA associated systemic vasculitis.

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/07/2009	Condition category Circulatory System	☐ 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
N0013129680

Study information

Scientific Title

Study objectives

To confirm that TNF a levels are elevated and correlate with disease activity in our cohort of vasculitis patients. To study the efficacy of infliximab in the treatment of ANCA associated vasculitis resistant to conventional immunosuppressive therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular: Systemic vasculitis

Interventions

This is a randomised controlled trial comparing Infliximab and placebo. Patients will receive either a single infusion of infliximab (5mg/kg) or placebo and will be followed for 3 months. Patients will continue to receive their current immunosuppressive therapy. Birmingham Vasculitis activity score (BVAS) will be used to judge the response. The responders will continue to receive infliximab (5mg/kg) infusion at 6, 14, 22 and 26 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Response will be judged by 50% reduction in BVAS score, CRP, ESR, patient and physician global score, reduction in prednisolone and concomitant immunosuppressive therapy.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/05/2006

Eligibility**Key inclusion criteria**

There are no previously published studies of infliximab in systemic vasculitis. However, a similar study of IVIG demonstrated a 50% reduction in disease activity after 3 months in a total of 34

patients (17 each in active and placebo group). Therefore in order to give a similar power of 0.8, we plan to recruit 40 patients (20 patients in each group) to give a significance level of 0.05 in a two-tailed study. Randomization will be done with minimisation protocol to ensure patients with similar characteristics in each group.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Positive pregnancy test or a planned pregnancy during treatment with infliximab or within 6 months of the last infusion
2. Prior administration of REMICADE or any other therapeutic agent targeted at reducing TNF (e. g., Etanercept, pentoxifylline, thalidomide or anti-CD4+ antibody) within the previous 3 months
3. A history of known allergies to murine proteins
4. Rapidly progressive glomerulonephritis
5. Severe pulmonary haemorrhage
6. History of Chronic/Serious infections, such as pneumonia, pyelonephritis and bacterial peritonitis in the previous 3 months. Less serious infections in the previous 3 months, such as acute upper respiratory tract infection (colds) or uncomplicated urinary tract infection if not fully resolved need not be considered exclusions at the discretion of the treating physician.
7. History of opportunistic infections such as herpes zoster within 2 months of screening. Evidence of active CMV, active Pneumocystis carinii, drug resistant atypical mycobacterium, etc.
8. Severe and/or chronic renal / pulmonary infections or sinusitis in the last 3 months
9. Known active tuberculosis requiring treatment during the last 3 years.
10. Documented HIV infection.
11. Any history of other autoimmune diseases.
12. Current signs or symptoms of severe, progressive or uncontrolled renal, hepatic, hematologic, endocrine, pulmonary, cardiac, neurologic or cerebral disease.
13. Known lymphoproliferative disease including lymphoma or signs suggestive of lymphoproliferative disease such as lymphadenoma of unusual size and localization or splenomegaly.
14. Any currently known malignancy or pre-malignant lesions or any history of malignancy within the past five years.

Date of first enrolment

04/06/2003

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Louise Coote Lupus Unit

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK)

Funder Name

Own account

Funder Name

NHS R&D Support Funding

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	01/04/2007		Yes	No