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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 21/07/2009	**Condition category** Circulatory System	

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
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/06/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

Study participating centre
Louise Coote Lupus Unit
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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?
Results article	results	01/04/2007		Yes	No