ISRCTN43525354 https://doi.org/10.1186/ISRCTN43525354

Anti-CD20 therapy for the treatment of chronic Graft Versus Host Disease

Submission date	Recruitment status
12/10/2006	No longer recruiting
Registration date	**Overall study status**
12/10/2006	Completed
Last Edited	**Condition category**
12/10/2006	Injury, Occupational Diseases, Poisoning

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
R'mabcGVHD

Study objectives
B cells contribute to the development of chronic Graft Versus Host Disease (cGVHD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Non-randomised trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Graft Versus Host Disease (cGVHD)

Interventions
Treatment with Rituximab once a week, for four weeks.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure

Proportion of complete and partial responses:
A complete response will be defined as a complete resolution of clinical evidence of chronic GVHD.
A partial response will be defined by an improvement in any of the affected organs.

Secondary outcome measures
Proportion of patients with a histological response.

Overall study start date
01/07/2006

Completion date
01/07/2008

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Steroid refractory chronic GVHD, including skin localisation
3. No other treatment apart from steroids and when applicable standard GVHD prevention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Relapse with a life expectancy of less than six months
2. Severe infections

Date of first enrolment
01/07/2006

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details
P.O. Box 85500
Utrecht
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3508 GA

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Industry

Funder Name
Koningin Wilhelmina Fonds (KWF) (The Netherlands)

Funder Name
Roche Nederland 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