

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

Submission date 12/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/10/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/10/2006	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Proportion of patients with a histological response.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration