

The safety and efficacy of anti-CD20 therapy (rituximab) in systemic sclerosis

Submission date 14/06/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/07/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/07/2009	Condition category 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

Protocol serial number
N/A

Study information

Scientific Title
The safety and efficacy of anti-CD20 therapy (rituximab) in systemic sclerosis: an interventional open-label single centre phase I trial

Acronym
BSSc

Study objectives

Considering the emerging role of B cells in systemic sclerosis, we will evaluate the safety and the efficacy of anti-CD20 therapy (rituximab) in systemic sclerosis patients, that had not previously responded to conventional therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Catholic University Institutional Committee approved on the 15th January 2006

Study design

Interventional open label single centre phase I trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Systemic sclerosis

Interventions

Patients will be treated with rituximab, two endovenous infusions of 1000 mg, 2 weeks apart, together with 100 mg methylprednisolone at each infusion. Clinical (skin score, disease activity and disease severity score, Global Health Status and Health Assessment Questionnaire, pulmonary function tests), biological (erythrocyte sedimentation rate [ESR], C-reactive protein, anti-CD20 positive cells in skin and blood, immunoglobulin levels and autoantibodies levels) and instrumental (lung computed tomography [CT] and echocardiography) data will be collected for at least 36 months.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Rituximab, methylprednisolone

Primary outcome(s)

Safety of the drug and efficacy on skin score (score that evaluates fibrosis on 17 skin areas: 0 = no skin involvement, 3 = severe thickening). All clinical evaluations will be performed every three months.

Key secondary outcome(s)

1. Efficacy of the drug on activity and severity indices
2. Global Health Status and Health Assessment Questionnaire
3. Evaluation of interleukin-6 (IL-6) and B-cell activating factor (BAFF) blood levels

4. Evaluation of the number of CD20-positive cells either in the blood either in cell infiltrate of skin biopsies

All clinical evaluations will be performed every three months. Pulmonary function tests will be performed every 6 months, while skin biopsies, echocardiography and lung HRCT every 12 months.

Completion date

01/12/2010

Eligibility

Key inclusion criteria

1. Systemic sclerosis patients aged 18 - 70 years , either sex
2. Diffuse cutaneous involvement
3. A worsening of skin score higher than 10% despite conventional therapies

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Key exclusion criteria

Severe pulmonary and cardiac involvement

Date of first enrolment

01/12/2005

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Italy

Study participating centre
Division of Rheumatology
Rome
Italy
00168

Sponsor information

Organisation

Catholic University of the Sacred Heart (Italy)

ROR

<https://ror.org/03h7r5v07>

Funder(s)

Funder type

University/education

Funder Name

Catholic University of the Sacred Heart (Italy) - Division of Rheumatology

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	01/02/2009		Yes	No
Results article	results	01/01/2010		Yes	No