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

Submission date	Recruitment status	[ ] Prospectively registered
14/06/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/07/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/07/2009	Musculoskeletal Diseases	

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
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 l trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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. Evaulation 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.

Overall study start date
01/12/2005

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
20+ participants

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)

Sponsor details
Division of Rheumatology
via Moscati, 31
Rome
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00168

Sponsor type
University/education

Website
http://www.unicatt.it/ucsc_EV.asp

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

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