Anti-TNF-alpha (Infliximab) in Complex Regional Pain Syndrome

Submission date	Recruitment status	Prospectively registered
27/01/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
27/01/2006	Completed	☐ Results
Last Edited	Condition category	Individual participant data
18/08/2009	Musculoskeletal Diseases	☐ 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

Protocol serial number N/A

Study information

Scientific Title

Acronym

InCRePaS study

Study objectives

Infliximab counteracts the increased synthesis of tumor necrosis factor alpha (TNF-alpha), after which inflammation will decrease and recovery of the disease occur.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics comittee

Study design

Randomised double blind placebo controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Complex regional pain syndrome type 1 (CRPS I)

Interventions

Subjects are assigned to receive either intraveneous Infliximab (5 mg/kg) or placebo 3 times in 6 weeks

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Reduction in clinical signs of regional inflammation

Key secondary outcome(s))

- 1. Improvement in subjective scores of quality of life
- 2. Normalisation of levels of inflammatory mediators in fluid of induced blisters

Completion date

31/12/2007

Eligibility

Key inclusion criteria

- 1. Men and women between 18 and up until 65 years
- 2. Established diagnosis of CRPS-1 according to the Bruehl/Budapest criteria
- 3. Are considered eligible according to tuberculosis screening criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

- 1. Disease related reasons
- 2. Abnormal laboratory findings
- 3. Adverse co-medication (such as corticosteroids, non-steroidal anti-inflammatory drugs [NSAIDs])
- 4. In general: concomitant congestive heart failure, pregnancy, receiving other recombinant products, history of serious infections, HIV, hepatitis B or C, abnormal chest radiograph, history of lymphoproliferative disease, opportunistic infection (e.g. herpes zoster), presence of a transplanted solid organ, history of alcohol abuse

Date of first enrolment

01/11/2005

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre Erasmus Medical Center

Rotterdam Netherlands 3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Industry

Funder Name

Centocor B.V. (Netherlands)

Funder Name

Ministry of Economic Affairs (Netherlands)

Alternative Name(s)

Ministry of Economic Affairs, Netherlands Ministry of Economic Affairs, EZ

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration