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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Reduction in clinical signs of regional inflammation

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

Overall study start date
01/11/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
24

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)

Sponsor details
Department of Anesthesiology
P.O. Box 2040
Rotterdam
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3000 CA

Sponsor type
Hospital/treatment centre

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

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