

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

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/08/2009	<b>Condition category</b> Musculoskeletal Diseases	<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

**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 committee

## 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 intravenous 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