

# 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
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/08/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**Contact name**  
Dr F.J. Zijlstra

**Contact details**  
Erasmus Medical Center  
Department of Anesthesiology  
P.O. Box 2040  
Rotterdam  
Netherlands  
3000 CA  
+31 (0)10 4635606  
f.zijlstra@erasmusmc.nl

## Additional identifiers

### 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

**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 intravenous 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