The sIL-2R level in patients referred with a suspicion of Complex Regional Pain Syndrome.
Comparison between those who are diagnosed with CRPS and those who are not.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20955

Source
Nationaal Trial Register

Brief title
ImPaCt

Health condition

Complex Regional Pain Syndrome

Sponsors and support

Primary sponsor: Center for Pain Medicine
Department of Anesthesiology
Erasmus MC University Medical Center Rotterdam
Source(s) of monetary or material Support: Sponsor/Initiatior

Intervention

Outcome measures

Primary outcome

sIL-2R level

Secondary outcome

CRPS severity score

Study description

Background summary

Rationale: the role of the immune system and specifically T-cells in the pathophysiology of Complex Regional Pain Syndrome (CRPS) is still unknown. Bharwani et al., 2017, showed an elevated level of the sIL-2R in CRPS patients vs healthy controls. This suggests increased T-cell activation in patients with CRPS. Further, the sIL-2R seems to be a good discriminator between CRPS patients and healthy controls with a sensitivity of 90% and a specificity of 89.5%. This finding warrants further investigation into the role of T-cells in the pathophysiology of CRPS. One limitation of the previous study was that the control group consisted of healthy blood bank donors with no history of chronic pain. It would be interesting to study the difference in sIL-2R level between CRPS patients and chronic pain patients without CRPS. This would increase the validity and consequently the diagnostic value of this marker in the diagnosis of CRPS.

Objective: to compare the level of the sIL-2R between patients who are referred to our Center for Pain Medicine with a suspicion of CRPS but do not fulfil the new IASP Clinical Diagnostic Criteria for CRPS and those who do fulfil the new IASP Clinical Diagnostic Criteria for CRPS and thus are diagnosed with CRPS.

Study design: cross sectional cohort study.

Study population: the study sample consists of adult patients who are referred to the Center for Pain Medicine at Erasmus MC University Medical Center Rotterdam with a suspicion of

CRPS.

Main study parameters/endpoints: the main study parameter is the blood sIL-2R level between patients diagnosed with CRPS and the patients who are not.

Study design

Day of visit at outpatient clinic

Intervention

Not applicable

Contacts

Public
K.D. Bharwani
Rotterdam
The Netherlands
Scientific
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Rotterdam
The Netherlands

Eligibility criteria

Inclusion criteria

The study sample consists of adult patients who are referred to the Center for Pain Medicine with a suspicion of CRPS.

In order to be eligible to participate in this study, the patient must meet all of the following criteria:

- Age ≥ 18 years.

- Only one limb is affected.

Exclusion criteria

A patient who meets any of the following criteria will be excluded from participation in this study:

- History of an auto-inflammatory or autoimmune disease.

- Current treatment with immunomodulating medication or treatment within the last 6 months.

- Ill in the past two weeks or at the time of visit.

- Knowledge of or confirmed pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-03-2018
Enrollment:	52
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-08-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44506
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7267
NTR-old	NTR7465
CCMO	NL62737.078.17
OMON	NL-OMON44506

Study results

Summary results
Bharwani KD, Dirckx M, Stronks DL, Dik WA, Schreurs MWJ, Huygen F. Elevated Plasma Levels of sIL-2R in Complex Regional Pain Syndrome: A Pathogenic Role for TLymphocytes? Mediators Inflamm. 2017;2017:2764261.