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.

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

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44506

Source
ToetsingOnline

Brief title
ImPaCt

Condition

- Other condition

Synonym
Reflex Sympathetic Dystrophy, Sudeck's Atrophy

Health condition

Complex Regionaal Pijn Syndroom.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Complex Regional Pain Syndromes, Diagnosis, Interleukin-2 Receptor alpha Subunit, T-lymphocytes

Outcome measures

Primary outcome

The main study parameter is the blood sIL-2R level between patients diagnosed

with CRPS and the patients who are not diagnosed with CRPS.

Secondary outcome

Association between the sIL-2R level and CRPS severity score.

Study description

Background summary

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 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 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.

Study objective

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

Study design

Cross sectional cohort study

Study burden and risks

This study carries a negligible risk related to venepuncture.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who are referred to the Center for Pain Medicine with a suspicion of CRPS.
Age * 18 years.
Only one limb is affected.

Exclusion criteria

History of an auto-inflammatory or autoimmune disease.
Current treatment with immunomodulating medication or treatment within the last 6 months.
Ill at the time of visit or recently been ill in the past two weeks.
Knowledge of or confirmed pregnancy.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

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

Ethics review

Approved WMO Date:	16-01-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20955
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62737.078.17
OMON	NL-OMON20955