

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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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20955

Bron

Nationaal Trial Register

Verkorte titel

ImPaCt

Aandoening

Complex Regional Pain Syndrome

Ondersteuning

Primaire sponsor: Center for Pain Medicine
Department of Anesthesiology
Erasmus MC University Medical Center Rotterdam

Overige ondersteuning: Sponsor/Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

sIL-2R level

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

Day of visit at outpatient clinic

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

K.D. Bharwani
Rotterdam
The Netherlands

Wetenschappelijk

K.D. Bharwani
Rotterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 \geq 18 years.

- Only one limb is affected.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Observatoneel onderzoek, zonder invasieve metingen

Onderzoeksmodel: Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving gestart

(Verwachte) startdatum: 06-03-2018

Aantal proefpersonen: 52

Type: Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 29-08-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44506

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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 T Lymphocytes? Mediators Inflamm. 2017;2017:2764261.