Looking for signs of inflammation in the brain of Chronic Fatigue Syndrome Patients

Gepubliceerd: 13-01-2016 Laatst bijgewerkt: 18-08-2022

Investigate if Chronic Fatigue Syndrome patients show signs of neuroinflammation, compared to Q-fever Fatigue Syndrome (QFS) patients and healthy neighbourhood controls.

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

Samenvatting

ID

NL-OMON27481

Bron
NTR

Verkorte titel
PET-CFS-1

Aandoening

Chronic Fatigue syndrome
Chronisch vermoeidheidssyndroom

Ondersteuning

Primaire sponsor: University Medical Center Groningen
9713 GZ Groningen, The Netherlands
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to evaluate whether there is an increased binding potential of the TSPO ligand [11C]PK11195, which is a marker for microglia activation in neuroinflammation, using PET in patients with chronic fatigue syndrome compared to Q-fever fatigue syndrome and healthy age- and sexe-matched controls.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Chronic Fatigue Syndrome (CFS) is a disease of unknown origin characterized by the presence of severe disabling fatigue for a period of at least six months. Patients often are diagnosed after having symptoms for several years, as there is no accurate diagnostic tool to diagnose CFS. This leads to a delay in starting treatment.

Q Fever fatigue syndrome (QFS) is a well documented state of prolonged fatigue following acute Q fever, an infection caused by Coxiella burnetii. Up to 20% of patients diagnosed with acute Q fever will eventually develop QFS, leading to a substantial burden for those who are affected. The clinical presentation of QFS sometimes shows overlapping symptoms with the symptoms of CFS patients. As is the case with CFS, research is still focused on finding better tools for diagnosing and treating this disease.

To improve diagnosis and treatment it is important to understand the mechanisms underlying these diseases. It has been proposed that (neuro)inflammation is an important factor in the development of CFS. We therefore aim to assess whether CFS and QFS are accompanied by the presence of neuroinflammation, using Positron Emission Tomography (PET).

Objective: The primary objective of this study is to evaluate whether there is an increased binding potential of the TSPO ligand [11C]PK11195, which is a marker for microglia activation in neuroinflammation, using PET in patients with CFS compared to patients with QFS and healthy age- and sexe-matched controls. Secondary objective(s) are to correlate the binding potential of [11C]PK11195 to (1) MRI measurements in the same subjects, (2) to fatigue severity using the CIS fatigue questionnaire and (3) to peripheral cytokine concentrations.

Study design: The design of this study is observational and case control, comparing the presence of neuroinflammation between CFS patients, QFS patients and healthy age- and sexe-matched controls.

Study population: The study population will consist of 10 CFS patients, 10 QFS patients and 10 healthy age- and sexe-matched controls subjects, which are neighbourhood controls. All subjects are females with an age between 18 and 60 years old.

Intervention: The subjects will undergo a PET scan with the TSPO ligand [11C]PK11195, which is a marker for microglia activation in neuroinflammation.

Main study parameters/endpoints: The main study parameter is the [11C]PK11195 binding potential in the brain.

Doel van het onderzoek

Investigate if Chronic Fatigue Syndrome patients show signs of neuroinflammation, compared to Q-fever Fatigue Syndrome (QFS) patients and healthy neighbourhood controls.

Onderzoeksopzet

There is one timepoint on which all measurements will be conducted.

Onderzoeksproduct en/of interventie

[11C]PK11195 (a ligand for the TSPO protein, upregulated in activated microglia cells) is injected in both patients, and healthy age- and sexe-matched controls. Binding of this tracer will be visualised on PET scan, indicating degree of neuroinflammation (activated microglia cells).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Control subjects:

- Female, between 18 and 60 years old;

- Healthy age- and sexe-matched controls, i.e. live in the same neighbourhood as the Chronic Fatigue Syndrome patient

Chronic Fatigue Syndrome (CFS) patients:

-Diagnosis according to the Dutch guideline on QFS [RIVM, Q-koortsvermoeidheidssyndroom];

- Female, between 18 and 60 years old;

- Score of ¡Ý40 on the subscale fatigue severity of the CIS (Checklist Individual Strength);

- Marked functional impairment assessed with the Sickness Impact Profile (SIP-8) and operationalised as a total score of ¡Ý700.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

All subjects:

- Women who are pregnant;

- Women who intend to get pregnant during the study;

- Use or having used psychotropic medication in the past six months;

- Alcohol or substance abuse in the past 3 months;

- Evident somatic/psychiatric co-morbidity;

- Presence of materials in the body that can be magnetized and cannot be removed;

- Participation in a scientific research study during the past year involving radiation.
- Use or having used Doxycyclin in the past 6 months;

CFS patients, additional
-History of Q fever;
-Vaccinated for Q fever.

Healthy volunteers, additional
-History of Q fever;
-Vaccinated for Q fever

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5515
NTR-old	NTR5642
Ander register	EudraCT : 2014-004448-37

Resultaten