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

No registrations found.

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

Summary

ID

NL-OMON27481

Source
NTR

Brief title
PET-CFS-1

Health condition

Chronic Fatigue syndrome
Chronisch vermoeidheidssyndroom

Sponsors and support

Primary sponsor: University Medical Center Groningen
9713 GZ Groningen, The Netherlands
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

- To correlate the binding potential of [11C]PK11195 to MRI measurements in the same patients (for example grey matter reduction).

- To correlate binding potential of [11C]PK11195 to fatigue severity using the CIS fatigue questionnaire.

- To correlate binding potential of [11C]PK11195 expression to peripheral cytokine concentrations.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

[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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2016
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results