The microbiome of Q Fever Fatigue Syndrome (QFS)

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To characterize the interaction between the gut microbiome, related metabolites, immune function, and perceived complaints in QFS-patients, CFS-patients, and healthy individuals.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON43296

Source
ToetsingOnline

Brief title
Microbiome of QFS

Condition

- Gastrointestinal infections
- Ancillary infectious topics

Synonym
Q fever, Q fever fatigue syndrom

Research involving
Human

Sponsors and support

Primary sponsor: Algemene Interne Geneeskunde
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars

Intervention

Keyword: Microbiome, Q fever, Q fever fatigue syndrome, QFS

Outcome measures

Primary outcome

The composition of the gut microbiome (classes of colonizing microorganisms)

will be compared between patients and healthy individuals.

Secondary outcome

The composition of circulating cytokines will be compared between cohorts

The composition of circulating metabolites will be compared between cohorts

The correlation of the gut microbiome (classes of colonizing microorganisms)

with the circulating cytokines and metabolites, and perceived complaints will

be compared within each cohort and between cohorts.

Study description

Background summary

Q fever fatigue syndrome (QFS) is a well documented state of prolonged fatigue following acute Q fever. Up to 20% of patients that are diagnosed with acute Q fever will develop QFS, leading to a substantial burden for the affected individuals. Current research mainly focuses on new methods for diagnosing and treating QFS, while its etiology remains elusive. A possible explanation for these persistent complaints could lie in the composition of the gut microbiome, a contributor to health and disease that over the past few years has been found influence different diseases. The different symbiotic microorganisms that together form the composition of the microbiome, each exert a different effect on their host through digestion of food, production of metabolites, alteration in membrane permeability, and stimulation of the local immune system and nervous system. Ultimately, the gut microbiome can influence the central nervous system, and vice versa, possibly contributing to the neurocognitive complaints that are often seen in QFS and chronic fatigue syndrome (CFS).

Study objective

To characterize the interaction between the gut microbiome, related metabolites, immune function, and perceived complaints in QFS-patients, CFS-patients, and healthy individuals.

Study design

This observational case control study will be performed at the Radboudumc, Nijmegen. The duration of the study is 1 year. The study will recruit and analyse 30 QFS-patients and 30 CFS-patients and compare this data with existing data from 30 healthy individuals, derived from the 500FG study (NL42561.091.12). We will use several approaches to answer the described research questions:
1. Metadata will be collected from all the participants using standard questionnaires on lifestyle. For patients, additional questionnaires on fatigue will be collected being the Checklist Individual Strength (subscale on fatigue) and the Sickness Impact Profile 8.
2. Microbiome analysis will be performed on faecal samples.
3. The function of the immune system and microbiome will be analysed through analysis of circulating cytokines and metabolites in unstimulated blood (plasma).
4. Clinical data will constitute Q-fever serology.

Study burden and risks

- No risks other than local hematoma related to a single venous puncture

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

Healthy controls (n=30)
- Female gender
- Age between 18 and 59 years old;QFS patients (n=30)
- Female gender
- Age between 18 and 59 years old
- LCI guideline on QFS diagnosis of QFS
- Score >=40 on the subscale fatigue of the Checklist Individual Strength (CIS) at time of diagnosis
- Severe functional impairment on Sickness Impact Profile-8 (SIP-8), defined as a SIP total score >=700 at time of diagnosis
- Fatigue duration for under 10 years;CFS patients (n=30)
- Female gender
- Age between 18 and 59 years old
- CDC diagnosis of CFS
- Score >=40 on the subscale fatigue of the Checklist Individual Strength (CIS) at time of diagnosis
- Severe functional impairment on Sickness Impact Profile-8 (SIP-8), defined as a SIP total score >=700 at time of diagnosis
- Fatigue duration for under 10 years, or recent progression of symptoms

Exclusion criteria

Healthy controls (n=30)
- No pregnancy / nursing
- No somatic or psychiatric comorbidity
- No complaints of fatigue (no complaints on lifestyle questionnaires)
- No use of medication in the last month (except oral contraceptives and / or paracetamol

- No vaccination during the last month before the study
- No substance abuse in the last 3 months before the study
- No history of Q fever, tested with serology;QFS patients (n=30)
- No pregnancy / nursing
- No somatic or psychiatric comorbidity
- No use of medication in the last month (except oral contraceptives and / or paracetamol
- No vaccination during the last month before the study
- No substance abuse in the last 3 months before the study;CFS patients (n=30)
- No pregnancy / nursing
- No somatic or pshychiatric comorbidity
- No use of chronic or acute medication during the last month before the study (except oral contraceptives and / or paracetamol
- No vaccination during the last month before the study
- No substance abuse in the last 3 months before the study
- No history of Q fever, tested with serology

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:	Recruitment stopped
Start date (anticipated):	21-02-2017
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	28-11-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL59116.091.16