ImpaQt * Pilot study on cognitive performance levels of patients with chronic Q-fever or Q-fever Fatigue Syndrome

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a pilot study will be performed to gain understanding in cognitive functioning in patients with chronic Q-fever or QFS compared to matched controls.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42926

Source
ToetsingOnline

Brief title
ImpaQt * Pilot study

Condition

- Bacterial infectious disorders

Synonym
Q-fever

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Stichting Q-support

Intervention

Keyword: Concentration, Long Term Impact, Memory, Q-fever

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameters will be cognitive

performance, measured with several neuropsychological tests

Secondary outcome

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Study description

Background summary

After the largest outbreak of Q-fever to date between 2007 and 2011, many infected persons in the Netherlands struggle with the effects from chronic Q-fever and Q-fever fatigue syndrome (QFS). There are indications that impairments in cognitive functioning may be present in these patients. However, this has never been studied in scientific research before.

Study objective

a pilot study will be performed to gain understanding in cognitive functioning in patients with chronic Q-fever or QFS compared to matched controls.

Study design

observational, cross-sectional study with assessment of a neuropsychological test battery. Descriptive analyses and multivariate models will be used to determine the relation between chronic Q-fever/QFS and cognitive performance.

Study burden and risks

Participants will complete several neuropsychological tests assessed by trained neuropsychologists. The assessment will take approximately one hour to perform, and includes widely used tests that measure information processing speed, memory, attention and executive functioning.

Contacts

Public
Selecteer

Geert Grooteplein Noord 21
Nijmegen 6525GA
NL
Scientific
Selecteer

Geert Grooteplein Noord 21
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with chronic Q-fever or Q-fever Fatigue Syndrome and controls from the general population. The pilot study will be performed in a subgroup of patients and controls who gave consent in a previous study (ImpaQt study, CCMO * Nijmegen number *2015-1919*).

Exclusion criteria

Patients with clinical depression (as measured with the Beck*s Depression Index in the ImpaQt study) will be excluded. Participants with medical conditions that cause cognitive dysfunction, (dementia, CVA or other brain injuries, etc .) as well as a history of major psychiatric disorders, will also be excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	01-09-2016
Application type:	First submission
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	NL58482.091.16