A phase 0 validation study in healthy male volunteers assessing the safety and tolerability of serial CSF sampling and to evaluate biomarkers related to Alzheimer*s disease in CSF and plasma

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The objective of this study is:• To investigate the safety and tolerability of 30 h continuous CSF sampling in healthy male subjects• To evaluate subject experiences of continuous CSF sampling using a standardized questionnaire.• To gain experience…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON36095

Source
ToetsingOnline

Brief title
serial CSF sampling study

Condition

- Neurological disorders NEC

Synonym
Alzheimer

Research involving
Human

Sponsors and support

Primary sponsor: QPS Netherlands B.V.
Source(s) of monetary or material Support: QPS Netherlands BV

Intervention

Keyword: CSF, males, safety, serial sampling

Outcome measures

Primary outcome

Investigate the safety and tolerability of 30 h continuous CSF sampling in

healthy male subjects

Secondary outcome

Evaluate subject experiences of continuous CSF sampling using a standardized

questionnaire. Gain experience with 30 h continuous CSF sampling. Evaluate ACh

as an example of a biomarker related to Alzheimer in CSF and plasma.

Study description

Background summary

Continuous CSF sampling gives the opportunity to correlate plasma concentrations of endogenous molecules with CSF levels to be utilized for PK/PD analysis. The purpose of this study is primarily to study the feasibility and especially the safety and the burden for the healthy volunteers of serial CSF sampling within the QPS environment in order to establish a standardized research tool for future drug development studies.

Study objective

The objective of this study is:
• To investigate the safety and tolerability of 30 h continuous CSF sampling in healthy male subjects
• To evaluate subject experiences of continuous CSF sampling using a standardized questionnaire.
• To gain experience with 30 h continuous CSF sampling

• To evaluate ACh as an example of a biomarker related to Alzheimer in CSF and plasma.

Study design

This is an explorative study with 30 h continuous CSF sampling in healthy males

Study burden and risks

This research method have been performed in clinical research with healthy volunteers and the tolerability in general was acceptable. A couple of complaints related to this procedure are known from other studies. These are identical to complaints related to lumbar puncture. These are headache (post-spinal headache or Post Dural Puncture Headache, PDPH), back and neck pain, pain at the location of the canula, dizziness, fainting and infection.
The risk of bleeding or nerve damage is very low.

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 men
Age 55-75
BMI 20-27 kg/m2

Exclusion criteria

Any clinical significant abnormalities

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2011
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2011
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL36849.056.11