A phase 0 study to investigate the effects of inhaled and intranasal lipopolysaccharide (LPS) on pro-inflammatory markers sampled by hypertonic saline sputum induction (SI) and nasal lavage (NAL) in healthy subjects. Part 1 with 0,9% NaCl.

Published: 16-08-2012
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON36988

Source
ToetsingOnline

Brief title
125633-CS-00186

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, COPD

Research involving

Human

Sponsors and support

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

Intervention

Keyword: healthy subjects, LPS, phase 0, sputum induction

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Intervention

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Study burden and risks

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Contacts

Public
QPS Netherlands B.V.

Hanzeplein 1, Entrance 53
Groningen 9713 GZ
NL
Scientific
QPS Netherlands B.V.

Hanzeplein 1, Entrance 53
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Healthy M/F subjects, aged 18-55 yrs.
- FVC, FEV1 >=80% ; FEV1/FVC ratio >=0.75.
- Oxygen saturation >=94% (pulsoximetry).
- Normal blood pressure (SBP 90-150, DBP 60-90 mmHg, inclusive) and pulse (45-100 bpm, inclusive)
- ECG without clinically relevant abnormalities.

Exclusion criteria

- History of upper and lower airway infection <=4 wks.
- Relevant atopy.

- Smoker (ex-smoker >1 yr, <10 packyrs).
- Positive metacholine inhalation test with a post challenge FEV1 decrease <20% (PC20), <16 mg/ml.
- History of clinically relevant pulmonary or cardiovascular disease.
- Positive pregnancy test or lactation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-08-2012
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

ID: 26578
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41617.056.12
OMON	NL-OMON26578