Vagus Nerve Stimulation in Healthy Humans

Published: 12-07-2007
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The primary objective of this study is to determine the anti-inflammatory potential of mechanical auricular Vagus nerve stimulation in healthy humans.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON31096

Source
ToetsingOnline

Brief title
Vagus Nerve Stimulation in Healthy Humans

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders
- Bacterial infectious disorders

Synonym
inflammation, inflammatory diseases

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Innovative Metabolics (USA)

Intervention

Keyword: Cytokines, Inflammation, Vagus

Outcome measures

Primary outcome

To obtain insight into the Vagus *tone* or the amount of Vagus nerve signals, heart rate variability will be determined. In addition, blood will be obtained before and at 0.5, 2, 5 and 24 hours after Vagus nerve stimulation for *ex vivo* tests evaluating a number of inflammatory responses.

Secondary outcome

Not applicable.

Study description

Background summary

Many common diseases are now recognized as *inflammatory disorders*. The pathology of these diseases, among which diverse pathological conditions such as rheumatoid arthritis, inflammatory bowel disease, pancreatitis and fulminant sepsis prominently feature, are considered to be mediated for a large part by uncontrolled inflammation. As a consequence, current therapies directed against these diseases at least in part rely on the administration of anti-inflammatory compounds. The nervous system, through the Vagus nerve, can downregulate inflammation in experimental animals in vivo by an interaction of acetylcholine, the principal neurotransmitter of the Vagus nerve, with macrophage cholinergic nicotinic acetylcholine receptors.

Study objective

The primary objective of this study is to determine the anti-inflammatory potential of mechanical auricular Vagus nerve stimulation in healthy humans.

Study design

20 healthy male subjects will be studied on two occasions (balanced assignment) separated by at least three weeks. On one occasion subjects will undergo

mechanical auricular Vagus nerve stimulation, whereas on the other occasion the Vagus nerve will not be stimulated. Vagus nerve stimulation will be administered using a commercially available oscillatory device at the right cymba conchae (located posterior to the crus of the helix in the frontal part of the ear with 100 % Vagus nerve innervation).

Intervention

Mechanical stimulation of the nervus Vagus in the right cymba conchae.

Study burden and risks

Vagus nerve stimulation is associated with a small risk for bradycardia. Venipunctures are associated with a small risk for a hematoma.

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

1. Male subjects between 18 and 50 years of age.
2. No clinically significant findings during physical examination and hematological and biochemical screening.
3. Normal electrocardiogram.
4. Able to communicate well with the investigator and to comply with the requirements of the study.
5. No medication.
6. Written informed consent.

Exclusion criteria

1. Known diseases, including previously documented cardiac arrhythmias.
2. A history of smoking within the last six months, or regular consumption of greater than three Units of alcohol per day.
3. Administration of any investigational drug within 30 days of study initiation.
5. Donation of blood within 60 days, or loss greater than 400 ml of blood within 12 weeks of study initiation.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	oscillatory device
Registration:	No

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL16944.018.07