Bone Turnover and Lipid Metabolism in Response to Vagal Nerve Stimulation

Published: 23-04-2012
Last updated: 26-04-2024

The objective is to study the effect of vagal nerve stimulation on bone turnover, lipid metabolism and inflammation.

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

Summary

ID

NL-OMON37555

Source
ToetsingOnline

Brief title
Bone turnover, lipid metabolism and the vagal nerve

Condition

- Other condition
- Lipid metabolism disorders

Synonym
bone turnover, lipid metabolism

Health condition

botmetabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: autonomic nervous system, bone turnover, lipid metabolism, vagal nerve stimulation

Outcome measures

Primary outcome

Bone turnover: The main outcome parameter is the change of serum concentrations

of bone turnover markers (procollagen type I N propeptide (P1NP) and C-terminal

crosslinking telopeptides of collagen type I (CTX)).

Lipid metabolism: The main outcome parameter is the change of the plasma lipid

profile (cholesterol, LDL, HDL, triglycerides).

Secondary outcome

NA

Study description

Background summary

The balance between the sympathetic and parasympathetic autonomic nervous system controls the activity of almost all organs. Recent experiments indicate that the autonomic nervous system also controls bone remodeling and lipid metabolism.
The sympathetic nervous system stimulates bone resorption whereas the parasympathetic nervous system possibly stimulates bone formation in rodents. Therefore, stimulation of the vagal nerve could prove an effective way to increase bone mass as a potential new treatment for osteoporosis.
Recent studies in rodents also show that the autonomic nervous system is involved in lipid metabolism. Additionally, increased sympathetic and decreased parasympathetic nerve activity correlates with factors of the metabolic syndrome, including hypertriglyceridemia in a large cohort of patients.

Conversely, in the normal population high parasympathetic nervous activity correlates with a low BMI. This could indicate a beneficiary effect of vagal nerve stimulation on the plasma lipid profile.

Study objective

The objective is to study the effect of vagal nerve stimulation on bone turnover, lipid metabolism and inflammation.

Study design

Prospective, longitudinal cohort study.

Study burden and risks

Patients undergo venous blood sampling at five different time points. The risks of venous blood sampling are negligible and the total amount of blood drawn will not exceed 125 ml in total (during 5 blooddraws).

Contacts

Public
Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients eligible for vagal nerve stimulator implantation
Age >18 years

Exclusion criteria

Incapability of giving informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2012

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	NL39889.018.12