Heart rate variability in patients with overactive bladder or stress urinary incontinence.

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The goal of the study is to investigate the difference between heart rate variability in patients with overactive bladder and patients with stress incontinence without overactive bladder, and also the difference in heart rate variability with empty...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational non invasive

Summary

ID

NL-OMON36299

Source
ToetsingOnline

Brief title
HRV in OAB and SUI

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
overactive bladder, urgency

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autonomic nerve system, heart rate variability, overactive bladder, stress urinary incontinence

Outcome measures

Primary outcome

Difference in LF/HF ratio between patients with IOAB and SUI

Difference in LF/HF between full and empty bladder in patients in both groups

Secondary outcome

Difference in total power (TP), SDNN, RMSSD, VLF, HF and LF between patients

with IOAB and SUI

Difference in total power (TP), SDNN, RMSSD, VLF, HF and LF between full and

empty bladder in patients in both groups

Study description

Background summary

Symptoms of overactive bladders syndrome are: frequency, urgency, nyctuia, with or without incontinence. The cause of idiopathic overactive bladder syndrome is unknown. There are indications pointing to a dysbalance of the autonomic nerve system. Previous studies have shown an overactivity of the parasympathethic system with empty bladder and overactivity of the sympathethic system with full bladder. In patients with stress incontinence there was a lack of sympathethic activity with full bladder.
The heart rate normally varies from beat to beat en the extent of variability reflects cardiac condition, but also the balance of the autonomous nerve system. Variability of the heart rate can be calculated with special software from a simple ECG.

Study objective

The goal of the study is to investigate the difference between heart rate variability in patients with overactive bladder and patients with stress incontinence without overactive bladder, and also the difference in heart rate

variability with empty bladder and full bladder in these two groups.

Study design

The study will be performed in female patients diagnosed with overactive bladder or stress incontinence.
A ten minute ECG will be performed in rest with empty bladder (just after voiding). Then the patient will be offered some drinks en when she has the feeling of a full bladder (urge to void), the second ECG will be recorded. Imediately afterwards the patient is allowed to void and the voided volume will be measured.
The ECG will be analysed according to the time domain method and the frequency domain method. The following parameters will be determined: total power, SDNN, RMSSD, the very low frequency (VLF) band, thelow frequency (LF) band and thehigh frequency (HF) band, The ration between LF and HF is a measure of autonomic nerve system balance.

Study burden and risks

During one visits 2 ECG's will be recorded. The time span between the 2 ECG's will depend on the speed of bladder filling. In between the measurements the patient is free to do an activity of choice. The ECG is not burdensome, invasive or harmful. Use of caffeine containing drinks and physical exercise are discouraged before the measurements.

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

Female sex
Age 18 - 75 years
Diagnosis of idiopathic overactive bladder or stress incontinence

Exclusion criteria

Antimuscarinic medication
Neurologic disease
cardiac disease
Medication influencing heart rate
Pregnancy
Urinary tract infection

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-11-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL33014.041.10