Evaluation of autonomic dysfunction: heart rate variability versus pulse rate variability

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Is pulse rate variability obtained from non-invasive continuous blood pressure measurements comparable to heart rate variability derived from an ECG signal during a battery of autonomic tests in healthy volunteers?

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

Summary

ID

NL-OMON33500

Source
ToetsingOnline

Brief title
HRV study

Condition

- Other condition
- Diabetic complications

Synonym
Autonomic dysfunction, diabetes mellitus

Health condition

evaluatie van de autonome functie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Autonomic nervous system, Cardiovascular reflex tests, Heart rate variability, Pulse rate variability

Outcome measures

Primary outcome

Correlation between pulse rate variability derived from non-invasive continuous

blood pressure measurements and heart rate variability derived from an ECG

during a standard battery of autonomic tests.

Secondary outcome

Continuous measurements of heart rate and blood pressure

Demographic patient variables: age, weight, length, comorbidities

Study description

Background summary

Recently the department of Anesthesiology started a study investigating cardiac sympathetic innervation and coronary blood flow regulation during anesthesia. This study will be conducted in healthy subjects and in diabetic patients with and without cardiovascular autonomic neuropathy (CAN). According to available literature CAN should be diagnosed with a battery of cardiovascular reflex tests in which beat-to-beat changes in heart rate are evaluated, i.e. the heart rate variation (HRV). HRV is usually obtained by measuring the time elapsed between two consecutive R-waves on the electrocardiogram (ECG). However, in the department of Anesthesiology a non-invasive continuous blood pressure measurement device (Nexfin) is available in which heart rate is determined from the blood pressure pulse rate. In the present study we therefore aim to investigate whether pulse rate variability (PRV) can be used as a reliable alternative for heart rate variability.

Study objective

Is pulse rate variability obtained from non-invasive continuous blood pressure measurements comparable to heart rate variability derived from an ECG signal during a battery of autonomic tests in healthy volunteers?

Study design

Prospective, observational trial.

Study burden and risks

Nexfin device:
Continuous blood pressure measurements will be performed by placing a finger cuff around the middle index of the left hand. The hand will be placed in a comfortable position when the volunteer is in a supine position. ECG-leads will be attached to the thorax. These techniques are associated with minimal discomfort for the patient.

Controlled breathing:
Volunteers will perform a cycle of metronome-controlled breathing to mimic ventilation conditions. This is regarded to induce minimal discomfort.

Valsalva maneuver:
The Valsalva maneuver will be performed by blowing into a manometer-controlled device that allows standardization of the pressure which induces the Valsalva effects. This measurement is associated with minimal discomfort.

Quick Standing test:
Volunteers are asked to quickly change from supine to standing position. This may induce some dizzyness, but in general this test will not cause other discomfort.

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

Sober males
Age 18-35 years
Healthy subjects
Informed consent

Exclusion criteria

BMI > 15 kg/m2 and < 35 kg/m2
Underlying cardiovascular diseases
Use of beta blockers or anti-hypertensive drugs
Diabetes mellitus
Use of coffee or cigarettes 12 hours before the measurements take place

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2009
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	22-10-2009
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	NL28800.029.09