The effect of device-guided breathing exercises on blood pressure in diabetic patients with hypertension;A randomized, double-blind controlled trial

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Objective: To determine the effect of a device slowing breathing (Resperate©) on office systolic blood pressure (SBP) in diabetic patients with treated hypertension with moderate BP control.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular hypertensive disorders
Study type	Interventional

Summary

ID

NL-OMON33106

Source
ToetsingOnline

Brief title
The effect of device-guided breathing exercises on blood pressure

Condition

- Vascular hypertensive disorders

Synonym
hypertension / high blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: diabetes kennis centrum

Source(s) of monetary or material Support: Medical Research Foundation (centre of excellence)

Intervention

Keyword: biofeedback, device guided breathing, hypertension, type 2 diabetes mellitus

Outcome measures

Primary outcome

Main study parameters/endpoints: The effect of the breathing device on SBP is

the main study parameter.

Secondary outcome

Secondary endpoints include diastolic blood pressure (DBP).

Study description

Background summary

SUMMARY

Rationale: Hypertension is an important risk factor of cardiovascular disease, especially in patients with type 2 diabetes mellitus (T2DM). A relatively recent development for the treatment of hypertension is the use of breathing exercises. Our previous studies with a breathing device did not show any positive results. However, these studies and other trials investigating the effects of breathing devices had not a double-blind design. Therefore, we want to perform a randomized, double-blind, controlled trial in a population of T2DM patients.

Study objective

Objective: To determine the effect of a device slowing breathing (Resperate©) on office systolic blood pressure (SBP) in diabetic patients with treated hypertension with moderate BP control.

Study design

Study design: A randomized, double-blind, controlled trial.

Intervention

Intervention: One group receives treatment with a breathing device (Resperate©) and the other group receives treatment with a *control* breathing device. The latter device does not try to alter the breathing pattern.

Study burden and risks

not to be expected

Contacts

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Scientific
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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 are required to meet the following criteria: known T2DM, over 18 years old, known hypertension with a systolic BP (SBP) between 130-170 mm Hg at the previous visit to the internal outpatient department and at the last visit to the internist (which is the same day as baseline measurement) and treated with one or more anti-hypertensive drugs, which have not been changed for the preceding three months. At baseline the SBP should be between 140-160 mm Hg, measured by the investigator according to the method described below.

Exclusion criteria

Patients with orthostatic hypotension, known heart failure (NYHA III-IV) and/or patients with pulmonary disease (for example asthma, chronic obstructive pulmonary disease and pulmonary fibrosis) will be excluded. Patients with insufficient knowledge of the Dutch language to understand the requirements of the study will be excluded. Additional criteria were hospitalization in the past 3 months, deafness, blindness and cognitive abilities deemed insufficient for operation of a study device

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2009
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2009
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL28100.075.09