

Validation of the Colin 8800C automated blood pressure monitor in patients with diabetes type 2 according to the International Protocol of the European Society of Hypertension

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The aim of this study is to evaluate the validity of the automated blood pressure device Colin 8800C in patients with type 2 diabetes according to the *International Protocol of the European Society of Hypertension.

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

Summary

ID

NL-OMON31467

Source

ToetsingOnline

Brief title

Validation of the Colin 8800C automated blood pressure monitor

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

diabetes, type 2 diabetes

Health condition

hypertensie

Research involving

Human

Sponsors and support

Primary sponsor: huisartsgeneeskunde

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: agreement, blood pressure, Colin 8800C, validity

Outcome measures

Primary outcome

Validation table

Secondary outcome

not applicable

Study description

Background summary

Although the mercury device has been used for over 100 years to measure the blood pressure, its use has been restricted in both Europe and the United States due to the toxicity of mercury. Therefore, automated blood pressure measuring devices are being used more and more.

At the *Diabetes Zorgcentrum Westfriesland*, the Colin 8800C is in use since 2004. This automated blood pressure measuring device was shown to be valid in healthy adults and children. However, the validity of the Colin 8800C in patients with type 2 diabetes is still unknown.

Study objective

The aim of this study is to evaluate the validity of the automated blood pressure device Colin 8800C in patients with type 2 diabetes according to the *International Protocol of the European Society of Hypertension.

Study design

Validation study in which the automated blood pressure device Colin 8800C is compared with a mercury manometer in patients with type 2 diabetes according to the *International Protocol of the European Society of Hypertension".

Study burden and risks

Blood pressure will be measured 14-16 times

Contacts

Public

Selecteer

van der Boechorststraat 7
1081 BT Amsterdam
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Scientific

Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

-diabetes type 2

-level of (systolic and diastolic) blood pressure

Exclusion criteria

arrhythmias or atrial fibrillation

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-02-2008

Enrollment: 33

Type: Actual

Ethics review

Approved WMO

Date: 25-01-2008

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	NL19807.029.07