# Home blood pressure monitoring in patients after carotid endarterectomy: a feasibility study

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vascular therapeutic procedures |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON45630

**Source**
ToetsingOnline

**Brief title**
Home blood pressure monitoring after CEA

### Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
arterial plaques, hardening of arteries

**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:** blood pressure, Carotid endarterectomy, home monitoring

## Outcome measures

### Primary outcome

The primary objective of this study is the feasibility, to assess the patient*s experience regarding performing home blood pressure measurements themselves and the use of cVitals in the first month after carotid endarterectomy. Patients experience will be assessed by means of a telephone survey based on a predefined questionnaire.

### Secondary outcome

The secondary objective, is the time from the start of the study to the appearance of a period of consecutive high blood pressure values who will exceed the predefined systolic threshold during the first month after hospital discharge after carotid endarterectomy and measured by the patients themselves. This predefined blood systolic threshold is based on the last performed Transcranial Doppler postoperative. Primary outcome is tIn case of a period of consecutive high blood pressure values who will exceed this predefined systolic threshold, will be requested to come to the outpatient clinic or emergency room for check-up of blood pressure.

Other outcomes are:

• The number of patients in which a significant change in blood pressure is measured during the first month at home compared to the last performed blood pressure measurement in the hospital.

• The number of patients in which (early) signals of cerebral hyperperfusion

are notified;

• The number of patients in which treatment needs to change based on the home

blood pressure measurements;

• The number of alarms (patient-specific; which could be set prior to hospital

discharge) that are correctly issued;

• The correlation of the post-operative measured blood pressure measurements

with the change in blood pressure rate (trend) measurements at one month.

• Percentage of patient adherence (number of actively sent blood pressure

measurements divided by the number of measurements requested for the study,

twice a day during 30 days.)

## Study description

**Background summary**

Carotid disease, which is usually caused by atherosclerotic narrowing of the internal carotid arteries, has been considered the underlying mechanism in approximately 20% of ischemic strokes. [1] Treatment of significant carotid stenosis is mainly aimed to decrease the risk of fatal or disabling stroke in patients with significant carotid stenosis and mostly consists of carotid endarterectomy. [2]

Several studies showed that arterial blood pressure is playing a significant role in perioperative care. Both systolic and diastolic blood pressure are related to stroke incidence and untreated hypertension is a risk factor.[4] Also the baroreceptor sensitivity is altered due to stroke or recent TIA, which can lead to difficult control of arterial pressure during carotid surgery and can even lead to cerebral hyperperfusion. The time period cerebral hyperperfusion can occur is between directly postoperative until 28 days after surgery.[5] Therefor, it is recommended to control the arterial blood pressure control strict intraoperative and directly postoperatively. [6]

However to our knowledge, there is little known about how the arterial blood

pressure develops in the first weeks after CEA when the patient is discharged to home. In the period between discharge and first visit to the outpatient clinic for regular postoperative check-up we don*t know anything about blood pressure variability/changes. Home blood pressure monitoring in CEA patients after hospital discharge could therefore provide solutions for the unmonitored period at home, while increasing the ability to detect patient deterioration earlier and will decrease the lack of knowledge on blood pressure development in the postoperative period.

**Study objective**

The primary objective of this study is to assess the patient*s experience of performing home BP measurements themselves (feasibility) in the first month after carotid endarterectomy. Furthermore, the secondary objective will be the time from the start of the study to the appearance of a period of consecutive high blood pressure values who will exceed the predefined systolic threshold during the first month after hospital discharge after carotid endarterectomy and measured by the patients themselves.

This current study is part of the research project on the creation of a safer care pathway from ICU to home for high risk patients by empowering doctors and nurses with remote monitoring equipment for early detection of patient deterioration.

**Study design**

This protocol describes an observational cohort study. Patients after carotid endarterectomy will be sent home with a home blood pressure monitor (HBPM) and asked to measure their BP every morning and evening under standardized conditions for a month. Readings will be automatically (or manually) saved in the cVitals Application (HMA) and sent via a safely secured connection to the care provider.

This observational study consists of two steps:
1. Prior to hospital discharge, patients will be trained how to measure their own blood pressure. They will receive an OMRON HEM-9210 blood pressure monitor and the cVitals App is being installed on an iPad which they will receive for lease.
2. After hospital discharge, patients will measure their blood pressure every morning and every evening for one month. Furthermore, they are stimulated to provide context information to a measurement whenever they feel it*s necessary, such as complaining of a headache, nausea, other.

**Study burden and risks**

In this feasibility study, all participants will be asked to measure their

blood pressure twice a day and send this data with help of software to save it in their medical chart. We will observe the blood pressure and observe the action taken by the participants in case of hypertension. (whether there will be contact between patient and outpatient clinic by notifications in HIX). In case of a period of consecutive persistent hypertension (multiple consecutive measurements) during at least 2 days, 4 measurements, exceeding the personal systolic blood pressure threshold with 15%, with or without complains, the (coordinating) investigator will call the participant and advise the participant to see a health care provider (vascular surgeon) on the outpatient clinic during office hours by making an appointment or to come to the emergency room in evening/night. At this appointment blood pressure measurement will repeated and might require adjustment in (blood pressure) therapy by their vascular surgeon/specialist . No treatment decisions will be made based solely on the readings of the blood pressure at home.

The device to monitor blood pressure has CE and FDA clearance as medical device. We suggest that OMRON HEM-9210 blood pressure monitor will cause no burden due its non-invasive and easy accessible use.

# 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

- Adult (>=18 yr of age)
- (a)symptomatic carotid artery stenosis due to atherosclerotic disease
- Treated by carotid endarterectomy
- mentally capable to make discissions

## Exclusion criteria

- ADL-dependent due to prior TIA or cerebrovascular accident (not able to measure the blood pressure twice a day)
- ADL-dependent because of other reasons besides above mentioned reason.
- Patients with carotid artery stenosis caused by other causes then atherosclerotic disease
- not mentally capable

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 11-10-2017 |
| Enrollment: | 30 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Bloodpressure device (OMRON HEM-9210) and application for registration of measured bloodpressure (cV |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 26-07-2017 |
| Application type: | First submission |
| 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 | NL59854.041.17 |