STEPWISE treatment of uncontrolled HyperTensioN in primary care: a cluster randomised trial.

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The objective is to investigate whether application of a stepwise work-up strategy in primary care patients with uncontrolled hypertension results in better blood pressure control in a cost-effective manner.

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

Summary

ID

NL-OMON50648

Source
ToetsingOnline

Brief title
STEPWISE HTN

Condition

- Vascular hypertensive disorders

Synonym
high bloodpressure not responding to medication, therapieresistant hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Julius Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Hypertension, Primary Care, Therapyresistant, Uncontrolled

Outcome measures

Primary outcome

The primary outcome is difference in 24-hour systolic BP between groups at 8 months follow-up.

Secondary outcome

- The percentage of patients with an office BP * 140/90 or a mean 24-hour BP *130/80 mmHg, measured at the endpoint (8 months).

- The time window (time from baseline) to reach a controlled BP during the study, defined as twice an office BP of *140/90 mmHg, or a mean 24-hours BP of *130/80 mmHg.

- The number and/or dosage needed of BP lowering drugs, measured during the study time.

- Referral to the medical specialist during the study time.

- Health care use and associated costs during the study period or bp control/bp related events.

- Quality of life as measured with the EQ5D and EQ-VAS at baseline and at the endpoint (8 months).

- Cost-effectiveness of the intervention expressed in terms of cost per patient reaching adequate BP level and cost per Quality Adjusted Life Year Gained.

- Self-reported BMI

Study description

Background summary

Hypertension is the most important risk factor for the development of cardiovascular diseases. Despite a wealth of evidence showing that lowering blood pressure reduces the risk of cardiovascular diseases in a cost-effective way, complications related to a poor blood pressure control still absorb 10% of the world's healthcare expenditure. In the Netherlands, where patients with hypertension are typically managed in primary care, only half of them reach an office systolic blood pressure target below 140mmHg. Currently, the management of hypertension is embedded within the cardiovascular risk management (CVRM). Guidelines on CVRM recommend first of all adequate blood pressure readings. Lifestyle advising (e.g. reducing intake of salt, licorice, and alcohol, correct overweight and perform more everyday excercise) should be optimalised, preferably on a patient-centered basis. Attention should be paid to adherence to medication. Finally, blood pressure lowering medication should be prescribed sensibly in those with high blood pressure (i.e. preferably once daily, considering multiple drugs from different classes at a low dose rather than less drugs at the highest dose). We expect that a a systematic diagnostic work-up in this would result in improved blood pressure control.

Study objective

The objective is to investigate whether application of a stepwise work-up strategy in primary care patients with uncontrolled hypertension results in better blood pressure control in a cost-effective manner.

Study design

This is a cluster-randomised controlled trial among 40 general practices. The practices will be randomised to either 'care as usual' or the intervention group (ratio 1:1) that will receive training in executing 'a protocolised stepwise work-up'.

Intervention

Trained GP's will execute a protocol involving a stepwise approach. The first step will be 24-hour blood pressure messurement to exclude white coat hypertension. Depending on how many steps a patient needs to achieve a controlled blood pressure, questionnaires will be filled out by the patient considering lifestyle, physical activity, salt intake and adherence. After that, together with the patient, the GP will decide whether improvement of adherence and adjustment of medication is possible. The patient will be referred to an internist in case the blood pressure is still uncontrolled at

the end of following this stepwise approach.

Study burden and risks

Participants are asked to fill out 3-4 questionnaires at baseline and after 8 months of follow-up. Also, in both groups 24-hour blood pressure measurement will be conducted at baseline and after 8 months of follow-up, this is a frequently used tool for general practitioners to measure the blood pressure, this will probably not be new for the participants. Patients might consider it as timeconsuming and as an intrustion into private life. In both groups, blood samples will be taken after 8 months and at baseline if the patients had lab testing longer than 3 months ago. This group of patients is used to give blood samples, we don't expect this to be a heavy burden. Possible complications of taking a blood sample may be a hematoma or an infection.
Participants in the intervention group will fill out, depending on how many steps they will need, another 4 questionnaires. They will have a maximum of 7 more consultations with their general practitioner or practice nurse. Therefore, the burden of time will be bigger than in the controlgroup. A psychological risk may be that the patient considers himself 'ill' or that filling out the questionnaires about nutrition or physical activity may be confrontating. The study population does not involve minors or incapacitated. The privacy of the participants will be assured.
We think that this is a low-risk study, with high positive impact in the treatment and consequences of hypertension. Therefore we think the burden and risks associated with participation will be less important, than the positive consequences of our study for the treatment of the patient.

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

Patients aged > 18 years and < 80 years with an office blood pressure > 140/90 mmHg, on at least two blood pressure measurements per visit and on at least two occasions in the last year despite prescription of three or more blood pressure lowering drugs of different classes at adequate dosage, with for each antihypertensive drug at least 1 prescription of 3 months. During the inclusion consultation, the office blood pressure should be > 140/90 mmHg (measured according to the guideline on *standardized office blood pressure measurement based on the NHG CVRM guideline).

Exclusion criteria

- A short life expectancy (< 6 months) as judged by the GP.
- Inability to understand or conform to the stepwise protocol.
- Unwillingness to provide a written informed consent.
- In case of suspicion of a hypertensive crisis (systolic blood pressure * 200 mmHg and/or diastolic blood pressure * 120 mmHg) the patient is referred for further evaluation. If a hypertensive crisis is excluded, the patient can be included in the study.
- Atrial fibrillation (because of difficulties to interpret 24 hour BP measurements)
- Pregnancy or breast feeding.
- Severe co-morbidity, which seriously interferes with diagnostic procedures or possible treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2018
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-03-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-01-2019
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO

Date:	11-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-08-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL61553.041.17