Stepwise treatment of uncontrolled high blood pressure in general practice

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22505

Source
NTR

Brief title
STEPWISE-HTN

Health condition

Therapyresistant
Uncontrolled
Hypertension
Primary Care

Therapieresistent
Ongecontrolleerd
Hypertensie
Eerste lijn

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Zon-Mw with additional funding from the Kidney Foundation

Intervention

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

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

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. 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. 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.

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.

Contacts

Public
Julius Centrum voor Gezondheidswetenschappen en Eerstelijns Geneeskunde. Divisie, Afdeling, Huispostnummer: stratenum 5.122

B. Kilic
P.O. Box 85500

Utrecht 3508 GA
The Netherlands
088-75-68099

Scientific
Julius Centrum voor Gezondheidswetenschappen en Eerstelijns Geneeskunde. Divisie, Afdeling, Huispostnummer: stratenum 5.122

B. Kilic
P.O. Box 85500

Utrecht 3508 GA
The Netherlands
088-75-68099

Eligibility criteria

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 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)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2018

Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion Date:	04-05-2018
Application type:	First submission

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
NTR-new	NL7099
NTR-old	NTR7304
Other	METC : 17/527

Study results

Summary results
None