Stepwise treatment of uncontrolled high blood pressure in general practice

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22505

Bron
NTR

Verkorte titel
STEPWISE-HTN

Aandoening

Therapyresistant
Uncontrolled
Hypertension
Primary Care

Therapieresistent
Ongecontrolleerd
Hypertensie
Eerste lijn

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: Zon-Mw with additional funding from the Kidney Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-05-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7099
NTR-old	NTR7304
Ander register	METC : 17/527

Resultaten

Samenvatting resultaten
None