Resistente HYpertensie: MEten voor Resultaat op Controle Tensie

No registrations found.

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

Summary

ID

NL-OMON26643

Source
Nationaal Trial Register

Brief title
RHYME-RCT

Health condition

Resistant hypertension, therapieresistente hypertensie

Sponsors and support

Primary sponsor: Erasmus Medical Centre
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

- Determine whether measuring drug levels combined with personalized feedback leads to a decrease in resistant hypertension after 12 months of follow-up.

Secondary outcome

- determine percentage of assumed resistant hypertension at baseline due to non-adherence

- Determine the percentage of patients with partial or non-adherence at baseline who are adherent after 12 months of follow-up

- Determine whether the number of required antihypertensive drugs is lower in patients who receive feedback on drug levels than in patients who do not.

- cost-utility of the intervention versus usual care in resistant hypertention

- The number of patients fulfilling the definition of resistant hypertension after 3 and 6 months

Study description

Background summary

Rationale: Resistant hypertension is a common health issue leading to high costs and suboptimal cardiovascular prevention. Non-adherence is one of the most common reasons, but proving non-adherence and, more importantly, improving adherence are challenging. We have developed a method to measure drug levels of the most commonly used antihypertensive drug in a dried blood spot (DBS) obtained by a finger prick.

Objective: To determine whether measuring drug levels combined with personalized feedback leads to a decrease in resistant hypertension after 12 months of follow-up due to improved adherence.

Study design: We will perform a randomised controlled trial in which half of the patients will undergo an intervention consisting of feedback on drug levels combined with supported problem-solving, while the other half will not receive any feedback on drug levels.

Study population: Patients with resistant hypertension (RH: uncontrolled hypertension despite a regimen of antihypertensive drugs from at least three classes including a diuretic). Patients need to use at least two drugs for which DBS-analysis is available. Patients who do not understand Dutch or Turkish or cannot give informed consent for another reason will be excluded. 392 patients will be included to be able to identify a difference in RH between the intervention group and the control group of 10%, taking into account a decrease in the control group due to study effect.

Intervention: Feedback of actual drug levels combined with supported problem solving: firstly, barriers to adherence will be discussed and suggestions for modular interventions tailored to the underlying cause of non-adherence will be made. A psychologist and a sociologist are involved to develop the training and to train the involved doctors to perform the supported problem solving. The control group will receive no feedback and supported problem solving.

Main study parameters/endpoints: Primary: the proportion of patients fulfilling the definition of resistant hypertension after one year. Secondary: the real number of patient with assumed resistant hypertension that is caused by non-adherence, cost effectiveness of the intervention, percentage of patients with resistant hypertension after 3 and 6 months

Study objective

Measuring drug levels combined with personalized feedback leads to a decrease in resistant hypertension after 12 months of follow-up due to improved adherence.

Study design

Inclusion

T = 0 months

T = 3 months

T = 6 months

T = 12 months

Intervention

Feedback of actual drug levels measured in a dried blood spot (DBS) obtained by a finger prick combined with supported problem solving: firstly, barriers to adherence will be discussed and suggestions for modular interventions tailored to the underlying cause of non-adherence will be made. The control group will receive no feedback and supported problem solving.

Contacts

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Eligibility criteria

Inclusion criteria

- Resistant hypertension: office blood pressure > 140/90 mmHg and 24h ABPM (ambulatory blood pressure measurement) daytime blood pressure > 135/85 mmHg despite a medication regimen of antihypertensive drugs from at least three classes including a diuretic.

- Use of at least two drugs for which DBS-analysis is available (enalapril, perindopril, losartan, valsartan, hydrochlorothiazide, spironolactone, amlodipine and nifedipine.

- Age 18 years and older

- Providing informed consent after reading patient information

Exclusion criteria

- Not providing informed consent or not capable of giving informed consent

- Kidney transplantation

- End-stage renal disease (eGFR<15 ml/min) „h

- Insufficient understanding of Dutch or Turkish language

- Secondary forms of hypertension (to be excluded according to local guidelines) except cases when a secondary form of hypertension has been established or is likely but chosen treatment is drug therapy (for instance primary hyperaldosteronism, renovascular hypertension).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018
Enrollment:	310
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-12-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50303
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6736
NTR-old	NTR6914
CCMO	NL63126.078.17
OMON	NL-OMON50303

Study results