Resistente HYpertensie: MEten voor Resultaat op Controle Tensie

Gepubliceerd: 27-12-2017 Laatst bijgewerkt: 15-05-2024

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

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

Samenvatting

ID

NL-OMON26643

Bron
Nationaal Trial Register

Verkorte titel
RHYME-RCT

Aandoening

Resistant hypertension, therapieresistente hypertensie

Ondersteuning

Primaire sponsor: Erasmus Medical Centre
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

Inclusion

T = 0 months

T = 3 months

T = 6 months

T = 12 months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	310
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50303
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten