Electronic monitoring of the use of antihypertensive drugs in patients with "drug resistant" hypertension

No registrations found.

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

Summary

ID

NL-OMON23458

Source
NTR

Brief title
MANGO study

Health condition

drugs, blood pressure, hypertension, compliance, treatment resistance, MEMS monitors

Sponsors and support

Primary sponsor: This is an investigator-driven study.
Principal Investigator: prof. dr. P.W. de Leeuw
Co-investigators: dr. P. Nelemans and dr. A.A. Kroon
Source(s) of monetary or material Support: Dutch Heart Foundation (protocol NHS 2005B101)

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the proportion of patients who reach the target levels at 6 months after inclusion (question 1 and 2) and at one year after inclusion (question 3).

Secondary outcome

Secondary outcome measures are:

- The proportion of patients with substantial decrease in blood pressure (SBP > 10 mm Hg and/or DBP > 5 mm Hg)

- The compliance rate defined as percentage of days with correct number of dosing and prescribed number and doses of antihypertensive drugs.

Study description

Background summary

The proposed study evaluates the effectiveness of a tool for minimising patient noncompliance with prescribed antihypertensive drugs and improving blood pressure control in these patients.
Early diagnosis and management of poor compliance enables distinction between non-compliers and pharmacological non-responders, and thereby facilitates rational decision making as to whether or not there is an indication for medication switches or dose increases

Background: Poor compliance is assumed to occur in 50% of patients with hypertension. There is a need for easy-to-use interventions that may improve compliance with prescribed antihypertensive medication and thereby clinical outcome (blood pressure).

Study objectives: The primary objective is to evaluate whether electronic monitoring of compliance can be used as a tool to improve compliance and thereby blood pressure control in that part of patients who do not respond to antihypertensive treatment due to clinically unrecognised compliance.

Secondary objectives are to evaluate whether a favourable effect a) can be sustained for at least six months and b) can be sustained after stopping of electronic monitoring.

Design: A randomised controlled trial comparing the effectiveness of electronic monitoring with usual care. In patients randomly assigned to the intervention group (n=120), each prescribed antihypertensive drug will be supplied in electronically monitored drug packages (MEMS® monitors, Aardex, Switzerland) during 6 months. Patients in the control group will receive usual care (without electronic monitoring) (n=30). Within the intervention group, a

second randomisation will take place at the end of the 6-month monitoring period: half of the patients will continue to use electronic monitors for another 6 months and the other half of patients will stop using electronic monitors.

Expected results: It is expected that electronic monitoring results in better blood pressure control in patients with clinically unrecognised compliance problems and reduces the need for more drugs and higher doses in these patients.

Study objective

Only 30% of patients, who are treated with antihypertensive drugs, reach target blood pressure levels. Noncompliance is considered to be an important cause of this lack of response to medication. In usual care, patients who do not respond to their medication often get prescriptions for other drugs or higher doses without considering whether they are compliant or not. This may result in unnecessary medication switches and dose escalations, but also to unnecessary diagnostic work-up, including costly and invasive diagnostic tests. The hypothesis is that electronic monitoring of compliance is an effective and easy-to-use tool to improve clinically unrecognised non-compliance and thereby clinical outcome in an early phase.

Study design

Follow-up. The duration of follow-up will be one year in all patients. Follow-up visits will be planned every two months after inclusion. During these visits, office blood pressure will be measured and the treating physician will decide whether or not changes in antihypertensive medication are indicated.

In the intervention group, a research nurse will be responsible for feedback of compliance data and advice to patients.

In both groups, 24-hour ambulatory blood pressure measurements (ABPM) will be performed at baseline and at the end of follow-up.

Intervention

MEMS monitors are caps of pill boxes which record time and date of every opening of the pill box. Assuming that every opening is a single dose intake, a dosing history of a patient can be recorded during the monitoring period and feedback of these data to the patients is feasible.

The electronic monitors record date and time of every opening of the pillboxes.
During follow-up visits, a research nurse will download the compliance data, discuss printed output with the patients, and if necessary will advice patients how to improve compliance by tailoring their medication use to daily schedules.

- The primary objective is to evaluate whether electronic monitoring of compliance can be

used as a tool to improve compliance and thereby blood pressure control in that part of patients who do not respond to antihypertensive treatment due to clinically unrecognised compliance.

Research questions:

1) To what extent does electronic monitoring of compliance with antihypertensive drugs (plus feedback on compliance) in patients with "drug-resistant" hypertension lead to normalisation of blood pressure when compared with usual care?

2) Can a favourable effect on blood pressure be sustained for at least six months?

3) Can a favourable effect on blood pressure be sustained after stopping electronic monitoring?

- Secondary objectives are to evaluate whether a favourable effect

a) can be sustained for at least six months and

b) can be sustained after stopping of electronic monitoring.

Contacts

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Eligibility criteria

Inclusion criteria

- Eligible are patients who have drug-resistent hypertension and have no renal artery stenosis (must have been excluded by conventional renal angiography or CT angiography or MR angiography).

Drug resistant hypertension is defined as having mean blood pressure >130/80 mm Hg according to 24-hour ambulatory blood pressure measurements (ABPM) despite the use of three or more drugs.

Exclusion criteria

- Patient that do not meet the inclusion criteria

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2006
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-06-2008
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	NL1314
NTR-old	NTR1363
Other	Dutch Heart Foundation : NHS2005B101
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A