Management of patients with uncontrolled arterial hypertension - the role of electronic compliance monitoring, 24 hour ambulatory blood pressure monitoring and candesartan /hydrochlorothiazide (HCTZ)

Submission date	Recruitment status No longer recruiting	Prospectively registered	
05/07/2006		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
26/07/2006	Completed	[X] Results	
Last Edited 24/09/2009	Condition category Circulatory System	Individual participant data	

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

The aim of the present study was:

- 1. To compare drug regimen compliance in hypertensives treated with combination therapy whose blood pressure (BP) was controlled versus uncontrolled after four weeks of self-monitored BP measurement.
- 2. To observe the consequences in uncontrolled patients of switching one drug of the combination therapy to candesartan/HCTZ (16 mg/12.5 mg) with and without a compliance intervention program.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval gained from the Ethics Committee of the university of Bonn on 12th December 2000 (reference No.:150/00).

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Resistant arterial hypertension

Interventions

Patients with oBP of more than 140/90 mmHg despite combination therapy were begun on microelectromechanical systems (MEMS) monitoring and self BP measurement for four weeks of run-in.

Of 62 such patients, 18 (29%) were normotensive according to self BP measurement and ambulatory BP measurement at four weeks (Group A); in the remaining 44 still uncontrolled

patients, candesartan/HCTZ was substituted for one of the combination therapy drugs, with half these patients receiving passive compliance monitoring (Group B) and the other half in the Drug Regimen Compliance (DRC) intervention program (Group C).

All groups were then followed for eight weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Candesartan and hydrochlorothiazide

Primary outcome measure

- 1. Drug compliance
- 2. Blood pressure

Secondary outcome measures

Not provided at time of registration

Overall study start date

02/01/2001

Completion date

02/01/2003

Eligibility

Key inclusion criteria

Patients with essential hypertension and office Blood Pressure (oBP) more than or equal to 140 /90 mmHg, despite combination therapy (more than two antihypertensive drugs)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

62

Key exclusion criteria

- 1. Pregnancy
- 2. Known intolerance of HCTZ or Angiotensin II Type One Receptor Blockers (AT1-Blockers)
- 3. Secondary hypertension

Date of first enrolment 02/01/2001

Date of final enrolment 02/01/2003

Locations

Countries of recruitmentGermany

Study participating centre Wilhelmstr 35-37 Bonn Germany 53111

Sponsor information

Organisation

Astra Zeneca (Germany)

Sponsor details

AstraZeneca GmbH Wedel Germany 22880

Sponsor type

Industry

ROR

https://ror.org/054q96n74

Funder(s)

Funder type

Industry

Funder Name

Astra Zeneca (Germany)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/08/2006		Yes	No