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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Thomas Mengden

Contact details
Wilhelmstr 35-37
Bonn
Germany
53111

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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 recruitment
Germany

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