

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

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| Submission date 05/07/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/07/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 24/09/2009 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Treatment

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(s)

1. Drug compliance
2. Blood pressure

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/054q96n74>

Funder(s)

Funder type

Industry

Funder Name

Astra Zeneca (Germany)

Results and Publications

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 |