Rotation of antihypertensive drugs in ethnic groups

Submission date	Recruitment status	Prospectively registered
19/12/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/12/2005	Completed	Results
Last Edited	Condition category	[] Individual participant data
03/11/2008	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number NTR384

Study information

Scientific Title

Acronym

ROTATIE

Study objectives

Inter-individual variation in antihypertensive drug response can be predicted through lifestyle, demographics and plasma drug levels.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, active controlled, crossover group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypertension

Interventions

Randomised, crossover trial. Six-week periods of antihypertensive drug treatment in monotherapy with three weeks washout. Drugs:

- 1. Lisinopril
- 2. Nebivolol
- 3. Barnidipine
- 4. HCl thiazide
- 5. Eprosartan

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lisinopril, nebivolol, barnidipine, HCl thiazide, eprosartan

Primary outcome(s)

- 1. Office blood pressure measured with an automatic device
- 2. Side effects measured with a questionnaire

Key secondary outcome(s))

No secondary outcome measures

Completion date

Eligibility

Key inclusion criteria

Subjects with uncomplicated hypertension between the ages of 36 and 60 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Serious hypertensive organ damage
- 2. Co-morbidity

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam Netherlands 1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type

Industry

Funder Name

Yamanouchi Europe BV (The Netherlands)

Funder Name

Solvay SA (Belgium)

Funder Name

Menarini Benelux NV (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration