ISRCTN08931855 https://doi.org/10.1186/ISRCTN08931855

Rotation of antihypertensive drugs in ethnic groups

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr R.P. Koopmans

Contact details
Academic Medical Centre
Department of Pharmacology and Therapy
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
r.p.koopmans@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2001

Completion date
31/12/2004

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
102

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)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

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

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