

Rotation of antihypertensive drugs in ethnic groups

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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