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Determinants of thiazide induced hyponatraemia in pre-exposed elderly - a controlled experiment

Submission date	Recruitment status	[X] Prospectively registered
16/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/07/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/08/2007	Nutritional, Metabolic, Endocrine	[ ] 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
N/A

Study information

Scientific Title

Study objectives
Thiazide-induced hyponatraemia is caused by impaired free water excretion either due to alterations in the Arginine Dihydrolase (ADH) - Arginine Vasopressin Receptor 2 (AVPR2) - Aquaporin-2 (AQP2) pathway or impaired renal sodium handling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Medical Ethics Committee of the AMC on the 16th August 2007 (ref: MEC 07/059).

Study design
Non-randomised, controlled experimental study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Thiazide induced hyponatraemia

Interventions
All subjects included in this controlled experiment will receive a single dose of Hydrochloorthiazide 50 mg. After that they will be monitored for 24 hours.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hydrochloorthiazide

Primary outcome measure
Effect of a single oral dose hydrochloorthiazide 50 mg intake on the serum and urine sodium, serum ADH, prostaglandin E2 and urinary aquaporin-2 excretion in elderly patients (aged 60 - 80 years) with previous thiazide-induced hyponatraemia (sodium less than 125 mmol/l) without another cause for their hyponatraemia and matched controls receiving a thiazide diuretic without hyponatraemia.

Urinary hydrochlorothiazide concentrations are measured to analyse differences in thiazide metabolism. The response to ADH will be assessed by expression of AVPR2 in a cell-culture and determine its activity by measurement of cyclic Adenosine Monophospahte (cAMP).

Outcomes will be measured at baseline (n = 0) and after 4, 8 and 24 hours.

Secondary outcome measures
To identify (elderly) patients who are at risk of thiazide induced hyponatraemia.

Outcomes will be measured at baseline (n = 0) and after 4, 8 and 24 hours.

Overall study start date
01/08/2007

Completion date
01/08/2008

Eligibility

Key inclusion criteria
1. Age 60 - 80 years
2. Previously admitted with thiazide-induced hyponatraemia
3. Patients must be willing and medically able to discontinue anti-hypertensive therapy six weeks before the study and for the duration of the study
4. Patients must be willing to be admitted for 24 hours and must be medically able to take the study medication
5. Patients must be willing to give informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
36

Key exclusion criteria
1. Other causes for hyponatraemia (e.g. heart failure, pulmonary disease, medication associated with hyponatraemia)

2. Renal dysfunction (estimated clearance less than 50 ml/min according to Cockroft-Gault)
3. Liver cirrhosis
4. Heart failure
5. Medication: antipressiva (Selective Serotonin Reuptake Inhibitors [SSRIs]), antiepileptica, prednisone, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), opioids, other diuretics (e.g. lasix, burinex, chloorthalidon, dytac)
6. Allergy for sulphonamide derivates
7. Therapy resistant hypertension (Blood Pressure [BP] greater than 140/90 mmHg while using three or more anti-hypertensive drugs)

Date of first enrolment
01/08/2007

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Vascular Medicine
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Charity

Funder Name
Dutch Kidney Foundation (Nierstichting Nederland) (The Netherlands)

Alternative Name(s)
Dutch Kidney Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

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