

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

Submission date 16/07/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/08/2007	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Thiazide induced hyponatraemia

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Hydrochlorothiazide

Primary outcome(s)

Effect of a single oral dose hydrochlorothiazide 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 Monophosphate (cAMP).

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

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 Cockcroft-Gault)
3. Liver cirrhosis
4. Heart failure
5. Medication: antidepressants (Selective Serotonin Reuptake Inhibitors [SSRIs]), antiepileptics, prednisone, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), opioids, other diuretics (e.g. lasix, burinex, chlorthalidone, dytac)
6. Allergy for sulphonamide derivatives
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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration