ISRCTN12215472 https://doi.org/10.1186/ISRCTN12215472

Lack of body water in the normal population

Submission date
13/10/2016

Recruitment status
No longer recruiting

Registration date
18/11/2016

Overall study status
Completed

Last Edited
15/01/2024

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Urinalysis (a test that evaluates a sample of urine) has been used to detect dehydration in sports medicine, but rarely in hospital patients. The kidneys hold onto water when a person is dehydrated, which can be detected by increasing osmolality (concentration of salts), urine-specific weight, darker urine colour, and a higher concentration of creatinine (a waste product from muscle activity). This approach could have a value in hospital care. The aim of this study is to investigate whether spot urine samples vary over the day and whether there is a relationship between dietary intake of water and how much the urine is concentrated.

Who can participate?
Hospital workers found to have concentrated or dilute urine when screened.

What does the study involve?
For the first week of the study, participants are asked to continue with their usual drinking habits and to keep a record of everything they eat and drink. They also provide urine samples daily which are assessed to detect dehydration. For the second week of the study, participants are asked to drink an additional 1.2 L of water every day. Throughout this time, participants record everything they eat and drink and provide urine samples every day. Before the study starts and then after the first and second week, participants undergo a medical examination in order to assess their general health.

What are the possible benefits and risks of participating?
Participants found to have concentrated urine at the start of the study may benefit from learning how much they should drink to have normally concentrated urine. There are no risks involved with participating.

Where is the study run from?
Södertälje Hospital (Sweden)

When is the study starting and how long is it expected to run for?
February 2016 to November 2017

Who is funding the study?
Mats Kleberg Foundation (Sweden)

Who is the main contact?
Professor Robert Hahn
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Contact information

Type(s)
Public

Contact name
Prof Robert Hahn

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol no 1

Study information

Scientific Title
Fluid retention in the normal population

Study objectives
1. Fluid retention in the normal population is caused by lack of sufficient water intake
2. Fluid retention can be reversed by increased water intake

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Board of Stockholm, 15/06/2016, ref: 2016/826-31

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Fluid retention

Interventions
For the first week of the study participants are asked to continue their normal eating and drinking habits and also to record their dietary/fluid intake and provide daily urine samples. These urine samples are assessed for urine colour, osmolarity, specific weight and creatinine.
In the second week of the study, participants are asked to ingest an additional 1.2 L of water per day. During this time participants continue to record dietary/fluid intake and provide daily urine samples for uranalysis.
Before the study starts and at the end of the first week and second week, participants undergo a medical examination with heart auscultation, blood pressure, the passive leg test and bioimpedance analysis of the body fluid volumes.

Intervention Type
Supplement

Primary outcome(s)
Composition of urine (urine colour, urinalysis of osmolality, specific weight, and creatinine) is assessed using urinalysis conducted on samples collected daily from baseline to the end of the second week.

Key secondary outcome(s))
1. Food and fluid intake throughout the study is assessed using food/fluid diaries throughout the both weeks of the study
2. Heart auscultation is assessed by a stethoscope at baseline and at 1 and 2 weeks
3. Blood pressure by Nexfin hemodynamic monitor at baseline and at 1 and 2 weeks
4. Passive leg test by Nexfin hemodynamic monitor at baseline and at 1 and 2 weeks
5. Bioimpednace for measurement of body fluid volumes at baseline and at 1 and 2 weeks

Completion date
30/03/2017

Eligibility

Key inclusion criteria
1. Healthy hospital workers
2. Found after screening to have either concentrated urine or diluted urine

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Medical disease requiring daily medication
2. Any kind of kidney disorder

Date of first enrolment
17/10/2016

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Södertälje Hospital
Research Unit
House 18, 6th Floor
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Sponsor information

Organisation
Södertälje Hospital

ROR

https://ror.org/0376t7t08

Funder(s)

Funder type
Charity

Funder Name
Mats Kleberg Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Robert Hahn (robert.hahn@sll.se)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2021	18/09/2020	Yes	No
Other publications	retrospective analysis	02/01/2023	20/12/2023	Yes	No
Other publications		12/01/2024	15/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes