

Lack of body water in the normal population

Submission date 13/10/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/01/2024	Condition category Signs and Symptoms	<input type="checkbox"/> 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
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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, osmolality, 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 measure

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.

Secondary outcome measures

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. Bioimpedance for measurement of body fluid volumes at baseline and at 1 and 2 weeks

Overall study start date

01/02/2016

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

Age group

Adult

Sex

Both

Target number of participants

40

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
Lagmansvägen 15
Södertälje
Sweden
152 86

Sponsor information

Organisation
Södertälje Hospital

Sponsor details
152 86 Södertälje
Södertälje
Sweden
152 86

Sponsor type
Hospital/treatment centre

Website
<http://sodertaljesjukhus.se>

ROR
<https://ror.org/0376t7t08>

Funder(s)

Funder type
Charity

Funder Name
Mats Kleberg Foundation

Results and Publications

Publication and dissemination plan
The result is planned to be published in an international scientific journal.

Intention to publish date

01/11/2018

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