

# Lack of body water in the normal population

<b>Submission date</b> 13/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/01/2024	<b>Condition category</b> 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  
robert.hahn@sll.se

## 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. Bioimpedance 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

Lagmansvägen 15

Södertälje

Sweden

152 86

**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?
<a href="#">Results article</a>	results	01/03/2021	18/09/2020	Yes	No
<a href="#">Other publications</a>	retrospective analysis	02/01/2023	20/12/2023	Yes	No
<a href="#">Other publications</a>		12/01/2024	15/01/2024	Yes	No