The development of a thirst provocation test using the AVP receptor antagonist Tolvaptan for quantification of thirst sensation in various patient groups (obese patients with and without a history of bariatric surgery, patients with congestive heart failure and patients with cranial diabetes insipidus as compared to healthy controls) and genotyping of the AVP receptor 2.

Published: 14-06-2012
Last updated: 26-04-2024

We aim to investigate thirst in the above mentioned patient groups, applying a Visual Analogue Scale (VAS) and, where ethically acceptable, a new thirst provocation test which we will develop in a group of healthy probands. Using these tools, we aim...

Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON38159

Source
ToetsingOnline

Brief title
Tolvaptan Thirst Research Project (TTReP)

Condition

- Heart failures
- Hypothalamus and pituitary gland disorders
- Gastrointestinal therapeutic procedures

Synonym
abnormal thirst, pathological thirst sensation

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: nog aan te vragen fondsen / subsidies

Intervention

Keyword: Bariatric surgery, Diabetes Insipidus, Heart failure, Thirst

Outcome measures

Primary outcome

The main objective of this study is to determine the effects of BS, heart

failure and diabetes insipidus on thirst sensation as measured on a visual

analogue scale (VAS).

Secondary outcome

The secondary objectives of this study are to determine the relation between

AVP2R genotype and thirst sensation.

Study description

Background summary

In the clinic, several patient groups seem to have altered thirst sensation, due to which they encounter problems in maintaining either a sufficient fluid intake or, contrarily, an adequate fluid restriction. Obesity and bariatric

surgery (BS) are both associated with kidney stone formation. Therefore, sufficient fluid intake is important in obese patients who underwent BS. However, our impression from the clinic is that fluid intake in BS patients is often insufficient. In contrast, patients with heart failure seem to have an increased thirst sensation, which causes noncompliance to fluid restriction. Finally, our impression from the clinic is that patients with cranial diabetes insipidus experience increased thirst despite normal serum osmolality.

Study objective

We aim to investigate thirst in the above mentioned patient groups, applying a Visual Analogue Scale (VAS) and, where ethically acceptable, a new thirst provocation test which we will develop in a group of healthy probands. Using these tools, we aim to investigate whether thirst sensation is pathological, or rather an adequate response to the clinical condition of these patients.

Study design

The thirst provocation test we aim to develop, involves the use of Tolvaptan (a novel, arginine vasopressin receptor (AVPR) antagonist). Blocking the antidiuretic effect of AVP by Tolvaptan causes hyperosmolarity and stimulation of AVP secretion, which causes thirst in healthy individuals. First, healthy probands meeting the inclusion criteria are invited to participate. The study will last until the calculated number of patients is included. The thirst provocation test will first be validated in 24 healthy probands. When the thirst provocation test is validated, we will include the three patient groups mentioned in the introduction, being obese patients, patients with heart failure and patients with cranial diabetes insipidus. The number of patients needed to obtain adequate statistical power will be calculated based on the results found in healthy probands. Of all patients and healthy participants, DNA will be isolated from blood and AVPR2 (encoding the AVP receptor 2) SNP analysis will be performed using Taqman® assay. The relation between VAS scores and AVPR2 genotype will be investigated using SPSS® 17.0 or Statgraphics® XVI.

Intervention

None

Study burden and risks

Burden: 5,5 hours at the hospital, 5 venapunctions of 10 ml each.
Risks: possible adverse effects of Tolvaptan, hematoma of venapunction.
Benefit: our research might provide an explanation for our patients* difficulties maintaining either a sufficient fluid intake or, contrarily, an adequate fluid restriction. Furthermore, our results might lead to therapeutic

options in the future.

Contacts

Public
Reinier de Graaf Groep

Reinier de Graafweg 3-11
2625AD
NL
Scientific
Reinier de Graaf Groep

Reinier de Graafweg 3-11
2625AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Informed consent signed by all healthy probands and patients
2. Male and female probands and patients, age 18 - 65 years
3. For obese patients with a history of Bariatric Surgery: Pre-BS BMI >27 Kg/m2
4. For obese patients without a history of BS: BMI >27 Kg/m2
5. For obese patients with a history of BS: operation at least 2 years ago, stable weight for at least a year

Exclusion criteria

1. Unwillingness to cooperate with the study procedures
2. History of an active malignancy
3. No written informed consent
4. Pregnancy
5. Breastfeeding
6. Urinary tract obstruction like benign prostate hyperplasia, or patients otherwise unable to void
7. (A history of) electrolyte disturbances or renal failure
8. Diabetes mellitus (as this can cause pseudohyponatraemia)
9. Lactose- or galactose intolerance
10. Clinical signs of dehydration
11. Failure to meet the inclusion criteria

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	14-06-2012

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36808.098.12