Medication for excessive urine production in patients treated with tolvaptan

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25236

Source
NTR

Brief title
Medication for excessive urine production in patients treated with tolvaptan

Health condition

ADPKD

cystenieren

polycystic kidney disease

polyuria

polyurie

tolvaptan

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Fund UMCG

Intervention

Outcome measures

Primary outcome

The primary outcome variable will be change in 24-hour urine volume

Secondary outcome

-Change in glomerular filtration rate (as measured with the iohexol plasma clearance technique)

-Change in plasma copeptin

-Tolerability of the study medication

Study description

Study objective

Metformin and hydrochlorothiazide attenuate polyuria in patients treated with tolvaptan

Study design

BL visit

2 week visit

5 week visit

8 week visit

Intervention

Subjects will be treated with hydrochlorothiazide, metformin and placebo for two weeks each, followed by one wash-out week, in random order. Hydrochlorothiazide will be initiated at 12,5mg QD, after one week the dose will be increased to 25mg QD if well tolerated. Metformin will be initiated at 500mg BID, after one week the dose will be increased to 1000mg BID, if well tolerated.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diagnosis of ADPKD, based upon modified Ravine criteria

2. Using tolvaptan 120mg daily

3. Age between 18 and 50 years

4. >45 eGFR (CKD-EPI)

5. Providing informed consent

Exclusion criteria

1. Patients who, in the opinion of the investigator may present a safety risk

2. Patients who are unlikely to adequately comply to the trial¡¯s procedures (due for instance to medical conditions likely to require interruption or discontinuation, history of substance abuse or non-compliance)

3. a. Patients taking medication likely to confound endpoint assessments (e.g. NSAID or diuretics such as furosemide or spironolactone)

3. b. Patients having concomitant illnesses likely to confound endpoint assessments such (e.g. diabetes mellitus for which medication is needed or diabetes insipidus)

4. Women who are pregnant or breastfeeding

5. Patients with known contra indications to the study medication such as

5. a. Hydrochlorothiazide: gout, hepatic impairment, illnesses that cause potassium loss, history of hypokalaemia, known allergy to hydrochlorothiazide

5. b. Metformin: Illnesses that can cause tissue hypoxia (e.g. recent myocardial infarction, heart failure, respiratory failure), known allergy to metformin

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	12
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6546
NTR-old	NTR6734
CCMO	NL2017HCTMet

Study results