Bumetanide for the Autism Spectrum Clinical Effectiveness Trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20585

Source
NTR

Brief title
BASCET

Health condition

Autism Spectrum Disorders (ASDs); Epilepsy

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Dutch Brain Foundation

Intervention

Outcome measures

Primary outcome

- Aberrant Behavior Checklist (ABC) Irritability Subscale

Secondary outcome

- World Health Organization Quality of life (WHOQOL-BREF)

- EQ5D-5L; EQ5D-Youth

- BRIEF

- Productivity Cost Questionnaire (iPCQ)

- Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P)

- ABC sub scales

- Repetitive Behavior Scale (RBS-V)

- Social Responsiveness Scale (SRS)

- Sensory Profile (SP-NL)

- SP School Sompanion (SP-SC)

Epilepsy related variables (if applicable)

- Seizure frequency

- Number of occasions rescue medication is necessary

Study description

Background summary

This is a multicenter, double-blind, randomized, placebo-controlled trial testing the effectiveness of three months bumetanide treatment in 172 children aged 5 to 15 years with ASD, with or without epilepsy. The primary endpoint is change in the ABC-I scale at Day 91. Usual care + bumetanide will be compared with usual care + placebo. Participants will be included in Groningen and Utrecht (the Netherlands).

Study objective

To confirm that twelve weeks of add-on treatment with bumetanide will improve daily life functioning and reduce behavioral symptoms related to hyperexcitability in children and adolescents with autism spectrum disorder and/or epilepsy.

Study design

Pre-treatment and screening (D-30 to Day0)

o Screening for eligibility

o Baseline measurements (all primary and secondary outcomes, except iPCQ and TiC-P)

Treatment (D0 to D91)

o Blood analysis at D4, D7, D14, D28, D56

o End of treatment outcome measurements D91 (all primary and secondary outcomes)
Washout (D91 to D119)

o End of washout outcome measurements D119 (all primary and secondary outcomes, except iPCQ and TiC-P)

Intervention

The investigational product (IP) consists of bumetanide 0.5 mg tablets or placebo, which will be provided as an add-on treatment, supplementary to the regular use of AEDs or other (allowed) comedications. Dose reductions to manage side effects will be allowed at any time. Due to the expected chance of frequent mild to moderate hypokalemia, all subjects will receive standard potassium supplementation during the 91 days of treatment. The treatment period will be followed by a wash-out period to evaluate return of symptomatology and reversibility of treatment effect.

Placebo product will be administered as comparator of the Bumetanide in exact similar tablets. The qualitative and quantitative composition in excipients of the Placebo product is comparable to that of Bumetanide 0.5 mg tablets.

Contacts

Public
University Medical Center Utrecht

D.M. van Andel
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31(0)88-7550776
Scientific
University Medical Center Utrecht

D.M. van Andel
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31(0)88-7550776

Eligibility criteria

Inclusion criteria

1. Males and females aged 5-15 years

2. Above ASD cut-off scores on the Social Responsiveness Scale and either a clinical ASD diagnosis based on DSM-5 (or DSM-IV) or an epilepsy diagnosis

3. Written informed consent

Exclusion criteria

1. Total IQ<55

2. Presence of a severe medical or genetic disorder other than related to ASD or epilepsy

3. Serious, unstable illnesses

4. Renal insufficiency, congenital or acquired renal disease with decreased concentration capacity and liver insufficiency

5. Behavioral treatment;

6. Treatment with psychoactive medications, including antipsychotics and AEDs, except methylphenidate, is allowed;

7. Treatment with NSAIDS, aminoglycosides, digitals, antihypertensive agents, indomethacin, probenecid, acetazolamide, Lithium, other diuretics, drugs known to have a nephrotoxic potential;

8. Documented history of hypersensitivity reaction to sulfonamide derivatives

9. Body weight <17 kg

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2017
Enrollment:	172
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45411
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6178
NTR-old	NTR6325
CCMO	NL58621.041.16
OMON	NL-OMON45411

Study results