Bumetanide for the Autism Spectrum Clinical Effectiveness Trial

Gepubliceerd: 13-01-2017 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20585

Bron
NTR

Verkorte titel
BASCET

Aandoening

Autism Spectrum Disorders (ASDs); Epilepsy

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Dutch Brain Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Aberrant Behavior Checklist (ABC) Irritability Subscale

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2017

Aantal proefpersonen:	172
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45411
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten