

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluating the effect of Bumetanide on brain functions in facial emotion recognition and attention to eyes, in children and adolescence with autism spectrum disorder

Protocol summary

Study aim

the effect of Bumetanide on the ability to recognize emotional faces (accuracy and processing speed) and attention to eyes in children and adolescents with autism spectrum disorder

Design

a pretest-posttest single group clinical trial.

Settings and conduct

After completing the consent form, the subjects received Bumetanide for three months. Evaluations performed on all subjects included Childhood Autism Rating Scale (CARS), Semi-structured Diagnostic Interview (K-SADS-PL), Social Responsiveness Scale (SRS), Wechsler Intelligence Scale for Children - Revised Form (WISC-R) and evaluation of ability to recognize emotional faces using event-related potential (ERP). Finally, the results of the evaluations were analyzed by repeated measures ANOVA, Bonferroni, paired t-test and Pearson correlation coefficient. Institute for Cognitive Sciences Studies

Participants/Inclusion and exclusion criteria

Participants: A group of 20 people Inclusion criteria: With autism spectrum disorder level 1 in the range of 7 to 16 years old, IQ above 70 Exclusion criteria: Karyotype abnormalities or neurological records including epilepsy and febrile seizures Allergy to sulfonamides liver or kidney dysfunction, heart disease

Intervention groups

Intervention group The subjects got for 3 month 1 mg Bumetanide (0.5 mg twice a day) purchased from the Niche Generics Limited Company in Ireland , which was provided weekly to their parents. They were treated with this medication for three months

Main outcome variables

Recognizing emotional faces; Attention to eyes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180901040915N1**

Registration date: **2019-07-06, 1398/04/15**

Registration timing: **retrospective**

Last update: **2019-07-06, 1398/04/15**

Update count: **0**

Registration date

2019-07-06, 1398/04/15

Registrant information

Name

Mehdi Tehrani-doost

Name of organization / entity

Institute for Cognitive Science Studies

Country

Iran (Islamic Republic of)

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+98 21 7629 1130

Email address

tehranid@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-05-05, 1397/02/15

Trial completion date

2018-09-21, 1397/06/30

Scientific title

Evaluating the effect of Bumetanide on brain functions in facial emotion recognition and attention to eyes, in children and adolescence with autism spectrum disorder

Public title

Effect of Bumetanide on brain function in autism spectrum disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed as a autism spectrum disorder, level 1 (needing support) according to DSM-V IQ above 70

Exclusion criteria:

Karyotype abnormalities or neurological records including epilepsy and febrile seizures A history of allergy to sulfonamides liver or kidney dysfunction, heart disease

Age

From **7 years** old to **16 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, , IRAN

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Province

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Postal code

1449614535

Approval date

2017-03-08, 1395/12/18

Ethics committee reference number

IR.IUMS.REC.1395.4537

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Evaluation of the latency and amplitude of brain signals faced with emotional faces

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Brain Event Related Potentials Recording

2

Description

Attention to eyes

Timepoint

Before the intervention and one week after the intervention

Method of measurement

Eye Track Recording

Secondary outcomes

1

Description

severity of the symptoms

Timepoint

One week before the intervention, sixth week of the intervention, and one week after the intervention

Method of measurement

Interview with the parents and completing the "Childhood Autism Rating Scale" questionnaire

2

Description

Evaluation of the communication and social relationships

Timepoint

One week before the intervention, sixth week of the intervention, and one week after the intervention

Method of measurement

"Social Responsiveness Scale" questionnaire completion

Intervention groups

1

Description

Intervention group: Receiving 1 mg (0.5 m.g in the morning, 0.5 m.g in the evening) Bumetanide (Purchased from Niche Generics Limited Ireland) twice a day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Dr. Tehranidoost`s Clinic

Full name of responsible person

Dr. Mehdi Tehranidoost

Street address

Third Floor, Baran Complex, Falsafi Alley, Shariati Street

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Institute for Cognitive Science Studies

Full name of responsible person

Dr. Javad Hatami

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Institute for Cognitive Science Studies

Proportion provided by this source

20

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

2

Sponsor**Name of organization / entity**

Cognitive Sciences & Technologies Council

Full name of responsible person

Dr. Majid Nili

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No. 35, Alvand Street, Argantin Square, Tehran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Cognitive Sciences & Technologies Council

Proportion provided by this source

70

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

3

Sponsor**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malakouti

Street address

Vice-Chancellor for Research and Technology, Iran
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

10

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Institute for Cognitive Science Studies

Full name of responsible person

Dr. Mehdi Tehranidoost

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mehdi Tehranidoost

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Institute for Cognitive Science Studies

Full name of responsible person

Raheleh Mollajani

Position

PhD student

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available