

# 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)

##### Phone

+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

##### City

Tehran

##### Province

Tehran

##### 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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**Email**

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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

**Street address**

Shahid Chamran Blvd, Safir Omid Blvd, Edalat Squar, Phase 4 of Pardis City

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1658344575

**Phone**

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**Email**

ICSS@iricss.org

**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

**Street address**

No. 35, Alvand Street, Argantin Square, Tehran

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research.project@cogc.ir

**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  
University of Medical Sciences, Kazem Besarati St.  
Kabiri Tameh Ave. Shahid Hemmat Expy, Tehran

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malakouti.k@iums.ac.ir

**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

**Street address**

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

Institute for Cognitive Science Studies

**Full name of responsible person**

Mehdi Tehranidoost

**Position**

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**Latest degree**

Subspecialist

**Other areas of specialty/work**

Psychiatrics

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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**

Master

**Other areas of specialty/work**

Neuroscience

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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