

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of camel milk and chicory inulin on clinical problems and oxidative stress biomarkers in children with autism spectrum disorders

Protocol summary

Study aim

The purpose of this study is to investigate the effects of camel milk and chicory inulin on severity of autism symptoms and enzymatic and non-enzymatic antioxidant activities in autistic children

Design

A Randomised, superiority, parallel group trial without blinded outcome assessment. 99 autistic children will be randomized into intervention and control groups by using stratified random assignment method.

Settings and conduct

99 autistic children of Mashhad centers for autism will be randomly assigned into control and intervention groups by using the stata software. At the baseline and the end of the study demographic questionnaire, Gilliam Autism Rating Scale (GARS) and Autism Treatment Evaluation Checklist (ATEC) will be completed by interviewing parents. A 5 mL blood sample will be taken from each subject before and after intervention for the measurement of blood antioxidant status and malondialdehyde (MDA) levels.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Autistic children Ages between 3-15 years old Exclusion criteria: Allergy to camel milk or chicory Inulin; subjects with Chronic Infectious Diseases, organic diseases or other Psychiatric and neurological disorders; consuming camel milk or pre/probiotics' products

Intervention groups

The intervention group 1 will receive camel milk and the intervention group 2 will receive chicory inulin powder for 7 weeks. The control group will not receive any intervention. The routine treatment will be continued in all the groups.

Main outcome variables

Changes in the serum levels of catalase, superoxide dismutase, total thiols and MDA and scores of GARS and

ATEC before and after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181227042147N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **prospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Seyed Jamal Mirmoosavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 8930

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-27, 1398/03/06

Expected recruitment end date

2019-06-01, 1398/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of camel milk and chicory inulin on clinical problems and oxidative stress biomarkers in children with autism spectrum disorders

Public title

The therapeutic effects of camel milk and chicory inulin in autistic children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

children with DSM 5 diagnosis of autism Ages between 3 and 15 years old

Exclusion criteria:

History of allergy to camel milk or chicory Inulin Chronic Infectious Diseases or AIDS Organic diseases Other Psychiatric and neurological disorders (for example: epilepsy, seizure, syndromes, ...) consuming camel milk consuming pre/probiotics' products

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, stratified random assignment method is used. The random assignment sequence is determined using the stata software.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of

Medical Sciences, Daneshgah 18 St, Danshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948974

Approval date

2018-11-24, 1397/09/03

Ethics committee reference number

IR.MUMS.REC.1397.215

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**

Autism disorder Severity

Timepoint

At baseline and after 7 weeks of intervention

Method of measurement

Gilliam Autism Rating Scale-GARS- Questionnaire

2**Description**

Evaluating the efficacy of treatment

Timepoint

At baseline and after 7 weeks of intervention

Method of measurement

Autism Treatment Evaluation Checklist (ATEC)

Secondary outcomes**1****Description**

Superoxide Dismutase (SOD) activity

Timepoint

At baseline and end of intervention (after 7 weeks)

Method of measurement

Spectrophotometry

2**Description**

Total thiols concentration

Timepoint

At baseline and end of intervention (after 7 weeks)

Method of measurement

Spectrophotometry

3

Description

Catalase activity

Timepoint

At baseline and end of intervention (after 7 weeks)

Method of measurement

Spectrophotometry

4

Description

Malondialdehyde (MDA)

Timepoint

At baseline and end of intervention (after 7 weeks)

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group 1: will receive for 7 weeks both their routine treatment and 10 ml/kg body weight camel milk daily in 2 divided doses. To comply with sanitary ordinances, camel milk will be pasteurized in the Food Sciences and Technology Complex of Ferdowsi University of Mashhad.

Category

Treatment - Drugs

2

Description

Intervention group 2: will receive for 7 weeks their routine treatment plus 4 g of chicory inulin powder daily. The chicory inulin powder in this trial is manufactured by Farasoodmand-Razi Knowledge Enterprise.

Category

Treatment - Drugs

3

Description

Control group: will receive their routine treatment without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mashhad centers for autism

Full name of responsible person

Seyed Jamal Mirmoosavi

Street address

Faculty of Persian and Complementary Medicine,
Pardis complex, Azadi Sq.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

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**

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Jamal Mirmoosavi

Position

PhD Candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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

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Full name of responsible person

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Assistant Professor

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Observance of ethics

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