Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

mirmj931@mums.ac.ir

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
Mashhad University of Medical Sciences
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

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Person responsible for updating data

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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