

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### Comparison of Mare Milk and Cow Milk in Children with Attention-Deficit/Hyperactivity Disorder

#### Protocol summary

##### Study aim

Comparison of Mare Milk and Cow Milk in Children With Attention Deficit-Hyperactivity Disorder

##### Design

This is a double blind crossover randomized clinical trial on children with attention-deficit/hyperactivity disorder. Patients will be chosen between 6 to 14 years old and both sex. Pediatric psychologist will diagnose ADHD patients with connors test.

##### Settings and conduct

This is a double blind crossover randomized clinical trial on children with attention-deficit/hyperactivity disorder. Pediatric psychologist will diagnose ADHD patients with connors test.

##### Participants/Inclusion and exclusion criteria

Patients will be chosen between 6 to 14 years old and both sex. Pediatric psychologist will diagnose ADHD patients with Connors test. patients with other psychologic or neurologic comorbidities; predominantly inattentive; history of prematurity or dysmaturity; history of smoking in mother during pregnancy would be the exclusion criteria.

##### Intervention groups

Patients will experience both of mare milk and cow milk consumption in two 45 days periods. In addition, they will have a 7 days wash out period between to main period. Patients will drink 250 ml milk every day.

##### Main outcome variables

Connors test will be evaluate before and after each period of milk consumption that will be filled out by parents and teachers. Drug dose, connors score and side effects, height and weight, appetite and sleep qualifications will be record. Primary essential information will be explained for the patients and their parents. Written consent will be obtained from the client and his/her parents , in addition researcher phone number will be given to them for any probable concern or problem. Finally, data will be analyzed by computer.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170823035862N1**

Registration date: **2018-01-16, 1396/10/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-16, 1396/10/26**

Update count: **0**

##### Registration date

2018-01-16, 1396/10/26

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3628 9681

##### Email address

z.jokar@ssu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-01-05, 1396/10/15

##### Expected recruitment end date

2018-04-08, 1397/01/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Mare Milk and Cow Milk in Children with

Attention-Deficit/Hyperactivity Disorder

## Public title

Comparison of Mare Milk and Cow Milk in Children with Attention-Deficit/Hyperactivity Disorder

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Attention deficit- hyperactive patients; Age between 6 and 14; Both sex;

### Exclusion criteria:

Other psychologic or neurologic comorbidities; Predominantly inattentive; Prematurity or dysmaturity; History of smoking in mother during pregnancy; Not interested in participating;

## Age

From **6 years** old to **14 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **32**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants, research director who will collect data and evaluate outcomes and pediatric psychologist, were blinded in this survey.

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of the research, Shahid sadoughi university of medical sciences

##### Street address

Shahid Sadoughi University building, Bahonar square, Shahid sadoughi Blvd., Yazd, Iran

##### City

yazd

## Province

Yazd

## Postal code

8916978477

## Approval date

2017-06-06, 1396/03/16

## Ethics committee reference number

IR.SSU.REC.1396.52

## Health conditions studied

### 1

#### Description of health condition studied

Attention-deficit/hyperactivity disorder

#### ICD-10 code

F90.0

#### ICD-10 code description

Disturbance of activity and attention Attention deficit: disorder with hyperactivity, hyperactivity disorder syndrome, with hyperactivity

## Primary outcomes

### 1

#### Description

Connors parent rating scale

#### Timepoint

In the beginning of the study, after the first period of milk consumption, before the second period of milk consumption, after the second period of milk consumption

#### Method of measurement

Connors Parent Questionnaire

### 2

#### Description

Connors teacher rating scale

#### Timepoint

In the beginning of the study, after the first period of milk consumption, before the second period of milk consumption, after the second period of milk consumption

#### Method of measurement

Connors teacher questionnaire

## Secondary outcomes

### 1

#### Description

Side effect

#### Timepoint

In the beginning of the study, after the first period of milk consumption, before the second period of milk consumption, after the second period of milk consumption

#### Method of measurement

Questionnaire form

## Intervention groups

### 1

#### Description

Intervention group: Intervention group in this double blind crossover randomized clinical trial on children with attention-deficit/hyperactivity disorder will be chosen from patients between 6 to 14 years old and both sex. Patients will experience both of mare milk and cow milk consumption during pharmacological treatment( Ritalin 1mg/kg) in two 45 days periods. In addition, they will have a 7 days wash out period between to main periods. Patients will drink 250 ml milk every day. Milk will be pasteurized at 63°C for 30 minutes. 32 patients were divided into 2 groups using a random number table: First group will consume mare milk for 45 days and after washout period( 7 days) use cow milk for 45 days.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Intervention group 2 ( second group) will consume cow milk for 45 days and after washout period( 7 days), use mare milk for 45 days.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Specialized Poly-Clinic Of Baghaei Pour

##### Full name of responsible person

Seyedeh Zahra Jokar Jandaghy

##### Street address

Department of Iranian Traditional Medicine, Faculty of Traditional Medicine, Shahid Sadoughi University of Medical Sciences, Ardakan, Yazd, Iran.

##### City

Yazd

##### Province

Yazd

##### Postal code

8951737915

##### Phone

+98 35 3723 8915

##### Email

z.jokar@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

zohreh musavi

#### Street address

Department of Iranian Traditional Medicine, Faculty of Traditional Medicine, Shahid Sadoughi University of Medical Sciences, Ardakan, Yazd, Iran.

#### City

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#### Province

Yazd

#### Postal code

8951737915

#### Phone

+98 35 3723 8915

#### Email

mosavi\_yazddent@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Yazd 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

Yazd University of Medical Sciences

##### Full name of responsible person

seyedeh zahra jokar jandaghy

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Department of Iranian Traditional Medicine, Faculty of Traditional Medicine, Shahid Sadoughi University of Medical Sciences, Ardakan, Yazd, Iran.

##### City

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##### Email

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

seyedeh zahra jokar jandaghy

**Position**

resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

seyedeh zahra jokar jandaghy

**Position**

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**Latest degree**

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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