

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of adding sarcosine to PMT (parental education management) treatment on the symptoms of coping disorder

Protocol summary

Study aim

1. Comparison of the mean score of child behavior in the intervention group with the mean score of the control group before, 2, 6 and 12 weeks after the intervention 2. Comparison of symptoms score mean of Oppositional defiant Disorder (ODD) in the intervention group with the mean score of the control group before, 2, 6 and 12 weeks after the intervention 3. Comparison of changes in the mean score of child behavior between the intervention and control groups before, 2, 6 and 12 weeks after the intervention 4. Comparison of changes in the mean score of symptoms of Oppositional defiant Disorder (ODD) in the intervention and control groups before, 2, 6 and 12 weeks after the intervention

Design

Two-group clinical trial with placebo group with double-blind randomization, 80 patients based on inclusion criteria

Settings and conduct

The doctor and the patient will not have information about the study (two blinds). Sarcosine and placebo powder is prepared by the Faculty of Pharmacy of Isfahan University of Medical Sciences in the form of 0.3 g capsules.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Boys and girls aged 6 to 12 years and diagnosis of Oppositional defiant Disorder (ODD) based on the DSM-V. 2. Parents' consent to participate in the study Exclusion criteria: 1- Disinclination of patients to participate in any stage of the study 2- No consumption of the drug accurately by patient 3- Patients for whom another diagnosis is made during the study.

Intervention groups

Sarcosine and placebo powder is prepared by Isfahan University of Medical Sciences in the form of 0.3 g capsules and will be prescribed to patients with the same appearance, color and smell at a dose of 0.03 g per kg daily.

Main outcome variables

Improve treatment

General information

Reason for update

Acronym

PMT

IRCT registration information

IRCT registration number: **IRCT20211022052836N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **retrospective**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name

Saeed Alvandian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

ghadamifa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2021-12-22, 1400/10/01
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of adding sarcosine to PMT (parental education management) treatment on the symptoms of coping disorder

Public title
Evaluation of the effectiveness of sarcosine to parental education management treatment on the symptoms of coping disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
1. Girl and boy children aged 6 to 12 years who have been diagnosed with coping disorder by a psychiatrist based on the DSM-V. 2. Parents' consent to participate in the study
Exclusion criteria:
1- Patients who do not want to continue participating in the study at any stage. 2- Patients who do not plan their medication according to the prescribed medication and do not take it accurately. 3- Patients for whom another diagnosis is made during the study.

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Actual sample size reached: **80**
More than 1 sample in each individual
Actual sample size in each individual: **80**
Due to the lack of a similar study, the required number of samples as a pilot in each group is considered 40 people.

Randomization (investigator's opinion)
Randomized

Randomization description
Due to the lack of a similar study, the required number of samples as a pilot in each group of 40 people are considered. These samples are easily selected from patients who refer to a pediatric psychiatric clinic.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and principal researcher Physician and patient will not have information about the study (two blinds)

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

814673461

Approval date

2022-07-23, 1401/05/01

Ethics committee reference number

IR.MUI.MED.REC.1400.162

Health conditions studied

1

Description of health condition studied

Oppositional Defiant Disorder

ICD-10 code

F91/3

ICD-10 code description

F91/3

Primary outcomes

1

Description

Percentage of people with Oppositional Defiant Disorder

Timepoint

At the beginning of the study, 2, 6 and 12 weeks after treatment

Method of measurement

Inventory Oppositional defiant behavioral Questionnaire (ODBI) and Demographic Information Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sarcosine powder in the form of 0.3 g capsules with a dose of 0.03 g per kg daily for the patient

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Pharmacy and Pharmaceutical of Isfahan
University of Medical Sciences Sciences

Full name of responsible person

Mojgan karahmadi

Street address

Hezar Jarib St., Isfahan University of Medical Sciences,
Isfahan, Iran

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8174673461

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+98 31 3668 8466

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+98 31 3668 8597

Email

karahmad@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan karahmadi

Street address

Hezar Jerib St., Isfahan University of Medical Sciences
and Health Services

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan karahmadi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

اصفهان، خیابان هزار جریب، دانشگاه علوم پزشکی و خدمات
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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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

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available