

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness syrup of rhubarb and ox tongue on patients with obsessive_ compulsive disorder mild to modrate

Protocol summary

Study aim

Evaluation of the effectiveness of rhubarb and ox tongue combination syrup in patients with obsessive ompulsive disorder

Design

This study is a double-blind randomized clinical trial that includes an intervention and treatment group. Information based on mild to moderate obsessive-compulsive disorder has been identified by DSM-5 criteria. The sample size was determined according to the information of similar studies such as the study of Sayyah et al. And also with the help of PASS software by observing power = 80%, $\alpha = 0.05$ and $D = 2$. The number 30 was set for each group.

Settings and conduct

This study is a randomized and interventional clinical trial that includes an intervention and treatment group. Patients with obsessive-compulsive disorder is identified by 5-DSM criteria, patients before therapeutic intervention after obtaining consent based on Questionnaires are evaluated and statistically analyzed.

Participants/Inclusion and exclusion criteria

Obsessive-compulsive disorder with 16th grade Yale Brown Questionnaire, Age 18 between 50 years At least a diploma History Receive at least 20 hours of exposure and prevent continuous response (individual or group), history of taking at least two drugs with Maximum recommended dose for at least 12 weeks satisfaction with participating in research

Intervention groups

Patients with obsessive-compulsive disorder identified by DSM_5 criteria and age18_50

Main outcome variables

Intensity of obsessive-compulsive disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200712048088N1**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **retrospective**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

Registration date

2020-12-06, 1399/09/16

Registrant information

Name

alaa masiha

Name of organization / entity

Country

Iran (Islamic Republic of)

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dr.alaamasiha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-24, 1399/07/03

Expected recruitment end date

2020-11-23, 1399/09/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness syrup of rhubarb and ox tongue on patients with obsessive_ compulsive disorder mild to modrate

Public title

Evaluation of the effect of rhubarb syrup and ox tongue flower on clinical signs of obsessive-compulsive disorder

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 50 years Minimum diploma education History Receive at least 20 hours of exposure and prevent continuous response (individual or group) History of taking at least two drugs with The maximum recommended dose for at least 12 weeks Satisfaction with participating in research. Diagnosis of obsessive-compulsive disorder (OCD) with the 16th grade Yale Brown Questionnaire

Exclusion criteria:

Psychosis or bipolar disorder Start a new psychological or psychiatric treatment or change the dose of medication, Reluctance to continue treatment

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants by statistical software

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad School of Medical Sciences

Street address

No 4 , Somayh 5 alley, Somayeh St

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617669416

Approval date

2019-11-20, 1398/08/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.391

Health conditions studied**1****Description of health condition studied**

obsessive-compulsive disorder mild to moderate

ICD-10 code

وسواس

ICD-10 code description

وسواس

Primary outcomes**1****Description**

obsessive-compulsive disorder mild to moderate

Timepoint

Initial evaluation, 4, 6, 8 weeks later

Method of measurement

Bill Brown Obsessive compulsive disorder Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: syrup of rhubarb and ox tongue (borage) for two months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ebn sina hospital

Full name of responsible person

Doctor Ali Talaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ali talaei

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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 univercity of medical scince

Full name of responsible person

Mohammadreza Noras

Position

professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

En Evaluation of the effectiveness syrup of rhubarb and ox tongue(borage)on patients with refractory obsessive-compulsive disorder

When the data will become available and for how long

2 years after graduation

To whom data/document is available

all the reaserchers

Under which criteria data/document could be used

There is not any considrable term

From where data/document is obtainable

مashhadunivercity of medical science

What processes are involved for a request to access data/document

There is not any considrable term

Comments

There is not any considrable term