

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the Effectiveness of *Sassurea custos* Oil on nocturnal enuresis of pediatric in Comparison with placebo, A Double-blind Study

Protocol summary

Study aim

Study of the Effectiveness of *Sassurea custos* Oil on nocturnal enuresis of pediatric

Design

A randomized, double-blind, placebo-controlled clinical trial

Settings and conduct

Study location: Mofid Hospital Study Material: In this study 60 children aged 5 to 15 years who were not treated due to nocturnal enuresis and had no renal disease, nervous system disease and urinary tract disease and presented to the project based on the opinion and examination of pediatric nephrology specialist. First, they provide the parents with the necessary information about the research project and after obtaining written consent they will be randomly divided into two groups of control and RCT.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children with a history of enuresis 2 times a week for 3 consecutive months; Age 5 or less than 15 years; Satisfaction with the project; No skin disease in areas intended for drug use; No organ disease associated with enuresis; noninclusion criteria: Frequent urinary tract infection; Previous surgery in the urinary tract; Having daily symptoms such as frequent urination, urinary incontinence; Any chronic degenerative disease involving the nerve or muscle and spinal cord injuries; A history of allergy to vegetable oils

Intervention groups

Intervention group: *Sassurea custos* Oil Control group: Sesame oil

Main outcome variables

Percentage of enuresis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190722044304N1**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Mojtaba Bigdeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4480 5405

Email address

bigdeli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the Effectiveness of *Sassurea custos* Oil on nocturnal enuresis of pediatric in Comparison with placebo, A Double-blind Study

Public title

Effectiveness of *Sassurea custos* Oil on nocturnal enuresis of pediatric

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a history of enuresis 2 times a week for 3 consecutive months
Ages 5 years or less
15 years
Satisfaction with the project
Lack of skin disease in areas for drug use
No organ disease associated with enuresis

Exclusion criteria:

Frequent urinary tract infection
Previous urinary tract surgery
Have daily symptoms like frequent urination, urinary incontinence
Any chronic degenerative disease involving the nerve or muscle and spinal cord injuries
A history of allergy to vegetable oils

Age

From 5 years old to 15 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

By throwing a coin, we determine who to give each drug to, and ultimately compare the results of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. The researcher is blind
2. The participant is blind

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

No, 12, 4 central alley, Alborz St, Ashrafi Esfahani Blvd

City

Tehran

Province

Tehran

Postal code

1477765666

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.SBMU.REC.1398.012

Health conditions studied

1

Description of health condition studied

Children's enuresis

ICD-10 code

F98.0

ICD-10 code description

Enuresis not due to a substance or known physiological condition

Primary outcomes

1

Description

Percentage of enuresis

Timepoint

At the beginning of the study one month later

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The consumable material is the *Costus*; its chemical composition is *Dehydrocostus*; The dose is 20 drops twice daily for one month; Local, on the bladder; *Costus* oil made by Department of Pharmacology, Faculty of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Category

Treatment - Other

2

Description

Topical chemical sesame oil
Linoleic acid and 20 drops twice daily topical use

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid hospital

Full name of responsible person

Mojtaba Bigdeli

Street address

No,12,4,center Aley,Alborz St,Ashrafi Blv

City

Tehran

Province

Tehran

Postal code

1477765666

Phone

+98 21 4480 5405

Email

mojtababigdeli57@gmail.com

2

Recruitment center

Name of recruitment center

Loghman hospital

Full name of responsible person

Mojtaba bigdeli

Street address

No,12,4,center Aley,Alborz St,Ahraphi Blv

City

Tehran

Province

Tehran

Postal code

1477765666

Phone

+98 21 4480 5405

Email

mojtababigdeli57@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi, PhD

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran. Post code: 19839-63113
Tel : +98 21 22 43 97 70 Fax : +98 21 22 43 34 55
Email: " Intl_office@sbmu.ac.ir "

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Email

Mpajouhesh@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mojtaba Bigdeli

Position

Assistan

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

NO,7 , 4, Central Alley, Alborz St,Ashrafi Esfahani Blvd

City

Tehran

Province

Tehran

Postal code

1477765666

Phone

+98 21 4480 5405

Email

Mojtababigdeli57@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mojtaba bigdeli

Position

Assistan

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No,12, 4 Central Ally, Alborz St, Ashrafi Blvd

City

Tehran

Province

Tehran

Postal code

1477765666

Phone

+98 21 4480 5405

Email

Mojtababigdeli@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mojtaba bigdeli

Position

Assistan

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No 12, 4 Central Ally, Alborz St, Ashrafi Esfahani blvd

City

Tehran

Province

Tehran

Postal code

1477765666

Phone

+98 21 4480 5405

Email

Mojtababigdeli@gmail.com

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