

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of coconut oil on mono symptomatic primary enuresis

Protocol summary

Study aim

Determine the effect of coconut oil on mono symptomatic primary enuresis

Design

This interventional study (randomized clinical trial) was randomized and taken into two groups of intervention and control in parallel. Initially, among children with enuresis above the age of 6 years who referred to Shahid Sadoughi Hospital and Clinic of Iranian Medicine, randomly and through the delivery of envelopes containing the sample or control And is equal, intervention samples and control are selected. The sample size is 110 people.

Settings and conduct

Shahid Sadoughi Clinic and Clinic of Iranian Medicine

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children with enuresis 6 years of age, lack of medication for complaints two weeks before the start of the study, obtaining consent to enter the study and continue; Possibility of patient following Exclusion criteria: There are other symptoms of the lower urinary tract, positive urine test for urinary tract infection during the study, presence of hematuria or proteinuria or glucosuria, obvious anatomical and congenital anomalies, a dangerous side effect of taking medication, patient's refusal to continue cooperation, creating an unpredictable problem for each One of the patients

Intervention groups

After entering the study, the patients in the intervention group are treated with coconut oil, with 6 drops of coconut oil in each of the areas of supra pubic, perineal, sacral and flaccid, and each night before bed in these areas by the child's parents Oil is being donated. In the control group, in the same areas, a placebo is used.

Main outcome variables

Enuresis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170423033605N2**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **prospective**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

Abolfazl Dehghanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3522 1596

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of coconut oil on mono symptomatic primary enuresis

Public title

The effect of coconut oil on enuresis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children with enuresis 6 years and older Do not take medication for complaints two weeks before the start of the study Gain consent to enter the study and continue it Possibility of patient tracking

Exclusion criteria:
There are other symptoms of the lower urinary tract Positive urine test for urinary tract infection during the study Hematuria Proteinuria Glucosuria Anatomical and congenital anomalies The creation of a dangerous side effect due to drug use Patient refusal to continue cooperation Create an unpredictable problem for each patient

Age
From **6 years** old to **16 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Through the delivery of envelopes in which they are written as sample or control.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, the main researcher who is also a clinical caregiver and outcome evaluator, were blinded in this study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address
Yazd, Shahid Dr. Bahonar Square, Shahid Sadoughi Blvd, Central Office of Yazd Shahid Sadoughi

University of Medical Sciences and Health Services

City
Yazd

Province
Yazd

Postal code
8916978477

Approval date
2016-12-26, 1395/10/06

Ethics committee reference number
IR.SSU.REC.1395.197

Health conditions studied

1

Description of health condition studied
enuresis

ICD-10 code
F98.0

ICD-10 code description
Enuresis (primary)(secondary) of non organic origin

Primary outcomes

1

Description
the frequency of nocturia per week

Timepoint
Before the intervention, 2 weeks, 4 weeks and 8 weeks after the intervention

Method of measurement
Questionnaire on the frequency of nocturia per week

Secondary outcomes

1

Description
age

Timepoint
Before intervention

Method of measurement
questionnaire

2

Description
sex

Timepoint
Before intervention

Method of measurement
questionnaire

3

Description
Complications of intervention

Timepoint
2 weeks, 4 weeks and 6 weeks after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Coconut oil: 6 drops of coconut oil are sacrificed in each of the supra pubic, perineal, sacral and flank areas, and each night before bed, these areas are anointment by the child's parents. Control group: Placebo: In the above areas, a placebo is used to anointment.

Category

Treatment - Drugs

2

Description

Control group: Six placebo drops are sacrificed in each supra pubic, perineal, sacral and analgesic areas and each night before bed, these areas are anointment by the child's parents.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghaeipoor Clinic

Full name of responsible person

Dehghanpoor Abolfazl

Street address

Safaieh - Riazi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dehghanpoor Abolfazl

Street address

Imam Khomeini Street, Faculty of Persian Medicine

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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

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

Abolfazl Dehghanpoor

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Majid Emtiazy

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

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

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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

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only available to scholars working in academia

Under which criteria data/document could be used

To promote the level of pediatric's health, especially psychologically Use of data is conditional on obtaining permission from the original researcher.

From where data/document is obtainable

Dr. Abolfazl Dehghanpour, Iranian Clinic of Medicine, Yazd-Ardakan- Imam Khomeini Ave., Faculty of Iranian Medicine, Postcode: 8951737915 Phone: 035-37238915-18 Email: tebsonati@ssu.ac.ir

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

Six months after the article was published in one of the ISI journals, the applicant can submit his request by email (at A.dehghanpour@ssu.ac.ir) and obtain permission to receive the data.

Comments