

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Dec 2022

The effect of caffeine restriction on enuresis in children 6 to 15 years old

Protocol summary

Study aim

The effect of caffeine restriction on enuresis in children 6 to 15 years old

Design

A clinical trial with a control group, with parallel groups, not blinded, randomized, no phase on 80 patients. For randomization, the regular randomization method was used one by one of the hospital patients.

Settings and conduct

The study will be performed on children aged 6 to 15 years in Golestan and Imam Reza (AS) hospitals from September 1400. To extract information, a checklist including children's demographic information and caffeine consumption and enuresis control is used. The amount of caffeine consumption in children was recorded based on the food frequency questionnaire and was calculated by N4 software. Counseling is given and the subjects are divided into two groups of control and intervention (caffeine restriction) by regular randomization (one in between). To collect the data, a table is set up and given to the children to record whether or not they have enuresis by mentioning the date. Children are asked to return one month later (to check for side effects and follow up on treatment) to have their enuresis checked or enuresis grade (severe / moderate / ..) checked. Children are followed up by not calling by phone and sending the enuresis recording table.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children 6 to 15 years old with primary enuresis with normal urinalysis and culture tests and ultrasound of normal kidneys and urinary tract

Intervention groups

The intervention group included restriction of consumption of caffeinated foods. The control group included no restriction on the consumption of caffeinated foods

Main outcome variables

Changes in the incidence and severity of primary enuresis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180401039167N3**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Bijan Rezakhaniha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 6431

Email address

reza.bijan1345@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of caffeine restriction on enuresis in children 6

to 15 years old

Public title

The effect of caffeine restriction on enuresis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with primary enuresis Normal urine analysis and culture tests Normal ultrasound of the kidneys and urinary tract Age range 6 to 15 years

Exclusion criteria:

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Regular person-to-person randomization in such a way that among the patients referred to the hospital with the initial enuresis complaint, we divide the eligible individuals into the study and intervention group one by one.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Medical Sciences of the Army of the Islamic Republic of Iran

Street address

Army University of Medical Sciences., Etemadzadeh St., West Fatemi St., Tehran., Iran

City

tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-09-14, 1400/06/23

Ethics committee reference number

IR.AJAUMS.REC.1400.151

Health conditions studied

1

Description of health condition studied

primary enuresis

ICD-10 code

F98.0

ICD-10 code description

Enuresis not due to a substance or known physiological condition

Primary outcomes

1

Description

Create enuresis

Timepoint

Measurement of enuresis at the beginning of the study and one month later

Method of measurement

Record enuresis in the calendar

Secondary outcomes

1

Description

The severity of enuresis

Timepoint

At the beginning of the study and a month later

Method of measurement

Record the number of enuresis days in the calendar

Intervention groups

1

Description

Intervention group: In children 6 to 15 years old with primary enuresis, in this group, the limit of caffeine consumption per day is a maximum of two cups (1-2 cups per 100 cc of light tea containing less than 30 mg of caffeine, which is provided by the software N4 is calculated) applies.

Category

Treatment - Other

2

Description

Control group: In this group, the consumption of caffeinated foods includes a glass of cocoa milk (100 cc cup contains 2 to 7 mg of caffeine) and two to three cocoa ice creams per week (weighing 75 grams, each containing an average of 2.5 mg of caffeine) and one to two cups of tea (2 100 cc cups of medium color tea

containing less than 50 mg of caffeine) or coffee (75 cc each contains 25 to 35 mg of caffeine) or cappuccino (each 75 cc cup contains 30 to 40 mg of caffeine) and 2 to 3 cans of cola a week (each 300 cc can contain 20 to 30 mg of caffeine) and one chocolate a day (50 g each pack contains approximately 10 mg of caffeine)) Or a chocolate cake (weighing 100 grams contains 5 to 7 mg of caffeine) or a chocolate biscuit (weighing 100 grams contains 4 to 6 mg of caffeine). In total, in the control group, the daily caffeine consumption was about 80 to 110 mg per day by N4 software.

Category

N/A

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

Imam Reza Hospital (501 Army)

Full name of responsible person

Bijan Reza Khaniha

Street address

Imam Reza Hospital (501 Army),, Etemadzadeh St.,West Fatemi St.,Tehran.,Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

lms@ajaums.ac.ir

2**Recruitment center****Name of recruitment center**

Golestan Hospital

Full name of responsible person

Bijan Reza Khaniha

Street address

Golestan Hospital.,Shahid Sayad Shirazi Highway.,Tehran.,Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 2277 1541

Email

lms@ajaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba yousefi zoshk

Street address

Army University of Medical Sciences., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

lms@ajaums.ac.ir

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

Yes

Title of funding source

Artesh 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**

Artesh University of Medical Sciences

Full name of responsible person

Bijan Rezakhaniha

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Army University of Medical Sciences., Etemadzadeh St.,West Fatemi St.,Tehran.,Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

reza.bijan@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

bijan rezakhaniha

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Army University of Medical Sciences., Etemadzadeh St., West Fatemi St., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

reza.bijan@yahoo.com

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

Artesh University of Medical Sciences

Full name of responsible person

bijan rezakhaniha

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Army University of Medical Sciences., Etemadzadeh St., West Fatemi St., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

reza.bijan@yahoo.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