

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of jujube consumption on heavy metal levels (Pb, As, Cd) of breast milk in lactating women

Protocol summary

Summary

This parallel randomized clinical trial will be conducted to determine the effect of jujube consumption on heavy metal levels (Pb, As, Cd) of breast milk in lactating women. The study participants included 40 breast-feeding women after postpartum who were randomly divided into two groups of (20 persons in each group), intervention and control. The sampling method is convenient and consecutive. Inclusion criteria are no history of chronic disease of mother, no smoking, no history of medication, residence in the city of Isfahan and written informed consent. Exclusion criteria will be no access to lactating-mothers in order to provide the breast milk after 2 month, no continuation of breastfeeding up to two month after delivery, any chronic disease incidence or drug usage during the study. Immediately after the child birth and breast milk flow, a sample of breast milk (10 cc) will be collected to determine the heavy metal levels (Pb, As, Cd as the main outcome variables). Intervention group will receive 15 g/day (once per day) Jujube for two months. Control group will not receive any placebo. After two months intervention, 10 cc of breast milk of each group of intervention and control, will be collected to measure the levels of Pb, As and Cd. To analyze the data, SPSS version 20, Independent T test and Paired T test will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302061434N8**
Registration date: **2013-12-09, 1392/09/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-09, 1392/09/18

Registrant information

Name

Roya Kelishadi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 1792 3060

Email address

kelishadi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2012-06-12, 1391/03/23

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of jujube consumption on heavy metal levels (Pb, As, Cd) of breast milk in lactating women

Public title

Effect of jujube consumption on heavy metal levels (Pb, As, Cd) of breast milk in lactating women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: no history of chronic disease of mother; no smoking; no history of medication; residence in the city of Isfahan (being residence in Isfahan at least from the last year) and written informed consent. Exclusion criteria: no access to lactating-mothers in order to provide the breast milk after 2 month; no continuation of breastfeeding up to two month after delivery; any chronic disease incidence or drug usage during the study.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Jujube is similar to dates, consists of maslinic acid, oleanolic acid, betulinic acid, glucose, resin, stigmasterol, sitosterol, tannin, essential fatty acids, 13 kinds of amino acids, selenium, cadmium, phosphorus and iron.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St.

City

Isfahan

Postal code

Approval date

2012-06-13, 1391/03/24

Ethics committee reference number

391142

Health conditions studied

1

Description of health condition studied

elevated levels of heavy metals in breast milk

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lead

Timepoint

at baseline and at the end of study (after 2 months intervention)

Method of measurement

µg/ lit Lab Kit

2

Description

Arsenic

Timepoint

at baseline and at the end of study (after 2 months intervention)

Method of measurement

µg/ lit lab kit

3

Description

Cadmium

Timepoint

at baseline and at the end of study (after 2 months intervention)

Method of measurement

µg/ lit lab kit

Secondary outcomes

empty

Intervention groups

1

Description

Jujube / day, 15 mg / oral / 2 months / for intervention group

Category

Treatment - Drugs

2

Description

Control group will not receive placebo.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Najmeh Hasanghalyaei

Street address

Esfahan-Motahari st

City

Esfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr.Peyman Adibi

Street address

Hezar Jarib St.

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr.Najmeh Hasanghalyaei

Position

Resident of Pediatrics

Other areas of specialty/work

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Person responsible for scientific inquiries

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Isfahan University of Medical Sciences

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty