

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The survey of consumption date fruit's effect on cervical ripening and outcome of labor in nulliparous women

Protocol summary

Summary

This is a randomized clinical trial study, to determine the effect of consumption date fruit on cervical ripening and outcome of labor in nulliparous women. Study participants are 110 primigravida pregnant women 18 to 45 years old with gestational age of 38, Bishop score of four or less and low risk pregnancy. Study participants were chosen by referring to Amir al-Momenin hospital and Clinic doctor in Semnan and they were put in two groups. 1. In Group of date fruit, 7 fresh and ripe date fruit without cores in daily consume from 38 weeks gestation until onset of labor and at the time of hospitalization 2. Control group (routine care). About a few days after intervention, 1 week after intervention, 2 weeks after, 3 weeks after that and at the time of hospitalization the elements were checked from cervical ripening and labour point of view. Women with rupture of membranes, high risk pregnancy and non-cephalic presentation are excluded. Finally, results will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207214529N11**

Registration date: **2013-08-04, 1392/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-04, 1392/05/13

Registrant information

Name

Nourossadat Kariman

Name of organization / entity

Shaheed Beheshti University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shaheed Beheshti University of Medical Sciences

Expected recruitment start date

2012-08-05, 1391/05/15

Expected recruitment end date

2013-07-01, 1392/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey of consumption date fruit's effect on cervical ripening and outcome of labor in nulliparous women

Public title

effect of consumption date fruit on cervical ripening

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Singleton pregnancy ;Gestational age from 38 weeks ;Bishop score of four or less; Not taking herbal or chemical drugs, Not having sexual intercourse and vaginal exam, 24 hours before and up to end of the study : Not having consumption of date fruit, 7 days before of the study;live in Semnan city . Exclusion criteria: noncephalic presentation;non Reactive non-stress test; An estimated weight of over 4000 grams;High risk pregnancy ;Diagnosed fetal anomalies ; Cephalo-Pelvic Disproportion; Abnormal vaginal bleeding

; Any known placental problem (placenta previa, placental abruption, placental insufficiency; Maternal infection and systemic chronic diseases ;Taking chemical/ herbal drugs in study time table ; Having sexual intercourse in study time table ; rupture of fetal membranes ;consumption of date fruit in control group

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shahid Beheshti University of Medical Sciences

Street address

Next to Taleghani hospital, Evin, Shahid Chamran Highway, Tehran, Iran

City

tehran

Postal code

-

Approval date

2012-09-16, 1391/06/26

Ethics committee reference number

122

Health conditions studied

1

Description of health condition studied

cervical ripening

ICD-10 code

O62.0

ICD-10 code description

Primary inadequate contractions

Primary outcomes

1

Description

cervical ripening

Timepoint

Before intervention, A few days,1 week,2 weeks ,3 weeks after intervention and at the time of hospitalization

Method of measurement

Examination

Secondary outcomes

1

Description

Delivery type

Timepoint

After delivery

Method of measurement

According to hospital records

2

Description

Using of oxytocin

Timepoint

Between admission in delivery room and delivery

Method of measurement

According to hospital records

3

Description

Duration of the first stage of labor (in minutes)

Timepoint

After finishing the first stage of labor

Method of measurement

Patient record

4

Description

Duration of the second stage of labor (in minutes)

Timepoint

After finishing the second stage of labor

Method of measurement

Observation and physical exam

5

Description

Neonatal Apgar

Timepoint

at last of study

Method of measurement

According to hospital records

6

Description

Duration of the third stage of labor (in minutes)

Timepoint

After delivery of fetus

Method of measurement

According to hospital records

7

Description

status of Amniotic fluid

Timepoint

at last of study

Method of measurement

Observation and physical exam

Intervention groups

1

Description

in Group of date fruit , consumption 7 fresh and ripe date fruit without cores in daily from 38 weeks gestation until onset of labor and at the time of hospitalization

Category

Prevention

2

Description

Control group: routine care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir ALMOMENIN Educational Center and Clinic of Doctor

Full name of responsible person

Maryam Yousefy Jadidi

Street address

Semnan - Amir ALMOMENIN Hospital Educational Center , unit labor

City

semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Simbar

Street address

Deputy of Research, School of Nursing and Midwifery

City

Tehran

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Yousefy Jadidi

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MSc student in midwifery

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Person responsible for scientific inquiries

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Semnan

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