

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of a Special Food (Fried Eggs with Grape Molasses) on Threatened Miscarriage in Combination with Conventional Therapies: A Randomized Clinical Trial

Protocol summary

Study aim

To determine the efficacy of a special food (fried egg with grape molasses) on threatened abortion.

Design

A randomized controlled clinical trial

Settings and conduct

90 patients will include in the study. Participants of this study were selected from the women referring to the perinatology clinic of Vali-asr hospital and Persian medicine clinic of Tehran University of Medical Sciences, with mild or moderate vaginal hemorrhage up to 16 wk.

Participants/Inclusion and exclusion criteria

Pregnant women with threatened abortion issue with mild to moderate severity of vaginal bleeding, gestational age below 16 weeks, after confirming the ultrasound and the absence of exclusion criteria (mother systemic illness, history of recurrent miscarriage, Open cervix more than two centimeters, absence of a normal gestational sac at 5 weeks gestational age, a yolk sac or cardiac activity at 7 weeks GA, incomplete abortion, missed abortion or multiple gestation sacs in ultrasound) are enrolled.

Intervention groups

1- The control group received 400 mg of progesterone suppository (Cyclogest®) with abstinence from sexual intercourse and physical exertion. Progesterone was used daily until two days once the bleeding had stopped. Then up to one week, suppositories were prescribed one day in between. 2- The intervention group received combined medicines: daily Khagineh and daily Cyclogest, abstinence from sexual intercourse, and physical exertion. Khagineh was also consumed daily, up to two days after discontinuation of bleeding/ spotting, and then was continued one day in between, up to one week.

Main outcome variables

the event of pregnancy losses before 20 weeks in both study arms

General information

Reason for update

Some changes in the method and study date

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040627248N1**

Registration date: **2016-07-09, 1395/04/19**

Registration timing: **prospective**

Last update: **2022-02-17, 1400/11/28**

Update count: **1**

Registration date

2016-07-09, 1395/04/19

Registrant information

Name

Fatemeh Moradi

Name of organization / entity

School of Traditional Medicine, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

fmoradi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Tehran University of Medical Sciences, University School of Traditional Medicine

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2018-11-01, 1397/08/10

Trial completion date

2018-11-01, 1397/08/10

Scientific title

The Effects of a Special Food (Fried Eggs with Grape Molasses) on Threatened Miscarriage in Combination with Conventional Therapies: A Randomized Clinical Trial

Public title

Effect of a special food (fried egg with grape molasses) on threatened abortion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women presenting with mild to moderate vaginal bleeding (using 2 Pads or less per day) Up to 16 weeks of pregnancy Normal ultrasound (including a normal gestational sac at five wk of gestation, yolk sac at six wk, or fetal heart activity at seven wk of gestation or later) Closed cervix in vaginal examination Singleton pregnancy Having consent to participate in the study Tendency to consume this special food (in intervention group) No fried eggs with grape molasses in routine diet food

Exclusion criteria:

Mother systemic illness such as fever, diabetes, chronic hypertension History of recurrent miscarriage Heavy vaginal bleeding (>2 pads soaked) Loss of conception tissue Open cervix (>2 centimeters) in vaginal examination Cervical lesions such as polyps or cervicitis Abnormal findings on ultrasound (absence of a normal gestational sac at 5 weeks gestational age, a yolk sac or cardiac activity at 7 weeks gestational age, incomplete abortion, missed abortion) Multiple gestation sacs Molar pregnancy Fetal or uterine anomalies Allergy or intolerance to eggs, grape molasses or progesterone The patient withdrew from the study

AgeFrom **12 years** old to **55 years** old**Gender**

Female

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **90**Actual sample size reached: **93****Randomization (investigator's opinion)**

Randomized

Randomization description

Blocks of six subjects carried out randomization and treatments' allocation with using stata software version 13. The list of random allocation of patients will be available only to the epidemiologist.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

None

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1416663361

Approval date

2016-06-12, 1395/03/23

Ethics committee reference number

IR.TUMS.VCR.REC.1395.121

Health conditions studied**1****Description of health condition studied**

Threatened abortion

ICD-10 code

O20.0

ICD-10 code description

Haemorrhage specified as due to threatened abortion

Primary outcomes**1****Description**

Determine the miscarriage rate (loss of an intrauterine pregnancy at ≤ 20 week's gestation) in patients with threatened abortion

Timepoint

Weekly follow-up until vaginal bleeding has been stopped
And follow-up at 20 weeks of pregnancy

Method of measurement

Self-designed form

Secondary outcomes

1

Description

The average duration of vaginal bleeding

Timepoint

Weekly follow-up until vaginal bleeding has been stopped
And follow-up at 20 weeks of pregnancy

Method of measurement

Self-designed form

Intervention groups

1

Description

Control group: They received 400 mg of progesterone suppository (Cyclogest®) with abstinence from sexual intercourse and physical exertion. Progesterone was used daily until two days once the bleeding had stopped. Then up to one week, suppositories were prescribed one day in between.

Category

Treatment - Drugs

2

Description

Intervention group: They received combined medicines: daily Khagineh and daily Cyclogest, abstinence from sexual intercourse, and physical exertion. Khagineh was also consumed daily, up to two days after discontinuation of bleeding/ spotting, and then was continued one day in between, up to one week.
"Khagineh Recipe: Beat together one egg and 25 g of grape molasses with salt until blended. Heat 5 g of pasteurized cow butter in a pan until it becomes hot. Pour the blended eggs onto the pan and brown on both sides."

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Perinatology clinic of Vali-e-Asr Hospital, Tehran
University of Medical Sciences (TUMS)

Full name of responsible person

Dr Fatemeh Moradi

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Imam Khomeini Hospital Complex, End of Keshavarz
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2

Recruitment center

Name of recruitment center

Traditional Iranian Medicine Ahmadiyah clinic, Tehran
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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, School of Traditional
medicine, Tehran University of Medical Scienc

Full name of responsible person

Dr Roja Rahimi

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School of Traditional medicine, Tehran University of
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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

Vice Chancellor for research, School of Traditional
medicine, Tehran University of Medical Scienc

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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Moradi

Position

physician/ PhD of Traditional Medicine

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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

School of Traditional medicine, Tehran University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Moradi

Position

physician/ PhD of Iranian traditional medicine

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address**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

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

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

Title and more details about the data/document

Ph.D. thesis + journal article

When the data will become available and for how long

five years

To whom data/document is available

Referrals to the library of the Faculty of Traditional
Medicine, Tehran University of Medical Sciences +
Visitors to the journal website

Under which criteria data/document could be used

Referrals to the library of the Faculty of Traditional

Medicine, Tehran University of Medical Sciences +
Visitors to the journal website

From where data/document is obtainable

Referrals to the library of the Faculty of Traditional
Medicine, Tehran University of Medical Sciences +
Visitors to the journal website

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

A common process in the libraries of Tehran University of
Medical Sciences + Journal website

Comments