# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

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School of Traditional Medicine, Tehran University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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**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
**Age**
From **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**
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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**
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**2**

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## Sponsors / Funding sources

**1**

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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**
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## Person responsible for updating data

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## 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**