

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Efficacy evaluation of Alcea angulata and Honey in Facilitating delivery

Protocol summary

Study aim

An Efficacy evaluation of oral Alcea angulata and Honey in Facilitating delivery

Design

Randomized clinical trial, phase 3, With a sample size of 90 individuals

Settings and conduct

The subjects referred to the maternity clinic of Ghaem and Umm al-Banin hospitals will be randomly divided into two groups of intervention and control. In intervention group, 2 grams of white khatmi flower with 12 grams of honey (twice daily) will be administered, while the same time the stripping will be done. The patient is again examined one week later at 40 week of pregnancy. If the bishop scores will not be increased more than 8 , administration of khatmi and honey will be continued and stripping will be repeated, then the patient will come back home. Every other day up to week 41, therapeutic affairs will be continued and Stripping will be repeated. she will be hospitalized in case of non-delivery and induction of childbirth will be carried out. In control group, only stripping is performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: single-embryo pregnancy / primy gravid / cephalic presentation / normal amniotic fluid (AFI greater than or equal to 5 cm) / lack of history of medical and obstetric / bishop scores less than 8 / maternal age between 18 and 40 years / lack of history of bad midwifery / Absence of previa placenta or placental adhesion Exclusion criteria: Pre-eclampsia after entering the study, incidence of drug complications, unwillingness of the patient to continue the study, indication of emergency delivery

Intervention groups

Intervention group: 2 grams (two times a day) of alcea angulata powder with 12 grams of honey, and also stripping will be done in each referral. Control group: stripping

Main outcome variables

Gestational age at delivery / interval of intervention to

delivery / time between admission and delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181106041578N1**

Registration date: **2018-12-19, 1397/09/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-19, 1397/09/28**

Update count: **0**

Registration date

2018-12-19, 1397/09/28

Registrant information

Name

fatemeh rahmaniivary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 8931

Email address

rahmanif941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy evaluation of Alcea angulata and Honey in Facilitating delivery

Public title

Efficacy of Khatmi in Facilitating giving birth

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant woman 39 to 41 weeks Without uterine contractions Primy Gravid Age between 40 - 18 years Single-embryo pregnancy Natural heartbeat of the fetus Cephalic presentation (Vertex) AFI greater than or equal to 5 cm No history of medical and obstetric medicine bishop Scours less than 8

Exclusion criteria:

Macrosomal embryo IUGR embryo Pre-eclampsia or blood pressure greater than 140/90 mm Hg Premature rupture of the amniotic bag Vaginal bleeding

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the samples to the two groups will be based on the random envelope method. Random numbers will be prepared and printed with the help of www.randomizer.org and placed inside a thick envelope. For each patient, one of these envelopes will be removed and according to the contents of the envelope, the person enters the intervention or control group

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**

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad, Azadi Square, Campus University, Faculty of Medicine, Faculty of Iranian Medicine and Mashhad Supplement

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2018-11-05, 1397/08/14

Ethics committee reference number

IR.MUMS.REC.1397.193

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

Post-term pregnancy

ICD-10 code

O48.0

ICD-10 code description

Post-term pregnancy

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

Delivery rate before week 41

Timepoint

Week 39, week 40 and then every other day

Method of measurement

baby's birth

Secondary outcomes**1****Description**

Gestational age at birth

Timepoint

Before and after 41 weeks

Method of measurement

day

2**Description**

Apgar Score

Timepoint

At birth and five minutes after birth

Method of measurement

0-15 based on Apgar measurement method

3**Description**

Maconeal amount

Timepoint

at Birth
Method of measurement
Observation (yes or no)

4

Description
Cesarean section

Timepoint
At the birth

Method of measurement
Observation (yes or no)

Intervention groups

1

Description
Intervention group: 2 grams of Alcea angulata with 12 grams of honey, orally, twice daily from 39 weeks of gestation to 41 weeks accompanied by stripping at weeks 39 and 40 and every other day to week 41

Category
Treatment - Drugs

2

Description
Control group: stripping at weeks 39 and 40 and every other day to week 41

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized Women's Hospital of Um Al-Benin (PBUH)
Full name of responsible person
Dr. Atiyah Mohammadzadeh Vatanchi
Street address
Zarineh Crossroads - Ayatollah Behjat 16
City
Mashhad
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Postal code
9177948564
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+98 51 3223 1061
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tim.pr@mums.ac.ir

2

Recruitment center
Name of recruitment center
Educational, Research and Therapeutic Center of Ghaem (AS)
Full name of responsible person

Dr. Atiyah Mohammadzadeh Vatanchi
Street address
Dr Ali Shariati Square, Beginning of Ahmadabad Street
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91766-99199
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Email
Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Taphaghghodi
Street address
University campus, Azadi Square
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Postal code
9177948564
Phone
+98 51 3882 8888
Email
med.faculty@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Rahmani Ivary

Position

Phd student of traditional Iranian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street addressAzadi Square, Campus University, Faculty of
Medicine, Faculty of Iranian Medicine and Mashhad
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Mahhad

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Email

rahmanif941@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Atieh Mohammadzadeh Vatanchi

Position

Academic Member - Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Rahmani Ivary

Position

Phd student of traditional Iranian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Email

rahmanif941@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/documentThe total potential data can be shared after
unidentifiable people**When the data will become available and for how long**

One year after publication

To whom data/document is available

Researchers and academic researchers

Under which criteria data/document could be used

To implement meta-analysis studies

From where data/document is obtainable

Send request via email

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

Send request via email

Comments