Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-embrio 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-embrio 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 ameniotic 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 Apagar 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

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3223 1061

Email

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

City

Mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Phone

+98 51 3840 0000

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

City

Mashhad

Province

Razavi Khorasan

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 address
Azadi Square, Campus University, Faculty of Medicine, Faculty of Iranian Medicine and Mashhad Supplement
City
Mahhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3884 8931
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
Street address
Dr. Ali Shariati Square, Beginning at Ahmadabad Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3840 0000
Email
vatanchia@mums.ac.ir

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
Street address
Azadi Square, Campus University, Faculty of Medicine, Faculty of Iranian Medicine and Mashhad Supplement
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3884 8931
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/document
The 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