Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of chamomile capsule on obstetrical outcomes in post term pregnancy

Protocol summary

Summary

The aim of this study is to determine the effect of oral chamomile capsules on obstetrics outcomes in post term pregnancy. This study will be accomplished randomized double blind clinical trial on low risk pregnant women with gestational age 41 weeks (40 weeks completely) based on LMP or ultrasound in first trimester of pregnancy, no history of recurrent spontaneous abortion, infertility and undesirable outcomes of pregnancy, single pregnancy, cephalic presentation, alive fetus, weight of fetus between 2500-4000 gram based on physical examination or ultrasonography, cervical bishop score less than 4, normal pelvic, normal BPP and NST, no sensivity to chamomile. Exclusion criteria are mothers who consume them is less than one capsule per day, more than one care session is absent, and appears allergic symptoms. Researchers would have attended to emergency ward and prenatal clinics of Shahid Akbar Abadi hospital. They will be selected who have inclusion criteria and give them informed consent and divided two groups with randomization. Prenatal care will perform to 40 weeks completely. If conditions of mothers will be good, bottle of oral chamomile or placebo (corn starch) capsule with checklist for record time of eating capsules pay to her. It would have been advised that they should take 3 capsules in a day for 7 days, since 40 weeks and 1 day. Standard dose of capsule will be fixed with pilot study on 10 participants, after that response dose is determined by traditional medicine specialist. Researcher is in contact with mothers every day and searches their obstetrical condition. They have to go to clinics for every 2 days. Enough education will be give for considering fetal movement 3 time in a day, it is mentioned them if they consider alarm symptoms like leakage, bleeding, sever abdomen pain, decrease fetal movement. They should record time of occurring them and call with researcher. Researcher will go to beside of mothers and record complete information and examination in questionnaire. When mother go to delivery room, vaginal examination consist of dilatation, effacement, effacement, station will record and draw partograph. Also the interval between eating first capsule and start delivery symptoms will record. During labor, these items will be recorded: Dilatation, effacement, during of active phase and labor stage. Fetal distress, meconium discharge, placenta abruption during labor, abnormal bleeding after childbirth, cesarean rate and cause of it, apgar score in first and fifth minutes of born and infant's hospitalization rate in NICU will record. All information record in SPSS software and analyzed with statistical exams. All of participants will assessment for days when start capsules. If symptoms of delivery don't start and there is no respond to treatment, management of delivery steps will performed according to guideline of Iran health ministry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062213737N1**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Fereshte Gholami darbarazi

Name of organization / entity

Tehran university of medical science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status
Recruitment complete
Funding source
Research's Assistance of Tehran University of Medical science

Expected recruitment start date
2013-06-25, 1392/04/04
Expected recruitment end date
2013-11-21, 1392/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of chamomile capsule on obstetrical outcomes in post term pregnancy

Public title
Effect of chamomile capsule in post term pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criterias: pregnant women 18-35 years old; Iranian nationality; have a body mass index less than 30 before pregnancy; low risk pregnancy; with getational age 41 weeks (40 weeks completely) based on LMP or ultrasound in first trimester; no history of recurrent abortion; infertility and undesirable outcomes of pregnancy; single pregnancy; cephalic presentation; alive fetus; weight of fetus between 2500-4000 gram based on physical examination or ultrasonography; cervical bishop score less than 4; intact membranous; normal pelvic according to researcher's exam; normall fetal heart rate and BPP and NST; no sensivity to herbal drugs and non-addicted persons. Exclusion criterias: those who consume them is less than one capsule per day, more than one care session is absent, and appears allergic symptoms.
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: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran university of medical science
Street address
Tehran, Keshavarz Blv, Ghods street, Central organization of university, Sixth floor, Research's assistance
City
Tehran
Postal code
1417653761
Approval date
2013-06-02, 1392/03/12
Ethics committee reference number
401/130/92/د

Health conditions studied

1

Description of health condition studied
post term pregnancy
ICD-10 code
048
ICD-10 code description
Post-dates

Primary outcomes

1

Description
obstetrical outcomes
Timepoint
2 weeks after intervention
Method of measurement
questionnair

Secondary outcomes

1

Description
Placental outcomes
Timepoint
During the first week of intervention and labor
Method of measurement
Observation and record in questionnaire

2

Description
Fetal outcomes
Timepoint
During first week of intervention
Method of measurement
Observation and Record questionnaire

3

Description
Maternal outcomes
Timepoint
During first week of intervention
Method of measurement
Examination, observation and record questionnaire

4

Description
Neonatal outcomes
Timepoint
To 10 days after delivery
Method of measurement
Observation and record in questionnair

Intervention groups

1

Description
Oral chamomile capsules, starting since 40 weeks of gestational age completely, primary dose of 3 capsules of 500 mg every 8 hours to do a pilot study
Category
Treatment - Drugs

2

Description
Placebo capsules, containing corn starch, 500 mg
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharloo hospital
Full name of responsible person
Fereshte Gholami Darbarazi
Street address
Tehran, Rah ahan Square, Behdari Square
City
Tehran

2

Recruitment center
Name of recruitment center
Shahid Akbar Abadi hospital
Full name of responsible person
Fereshte Gholami Darbarazi
Street address
Tehran, Molavi Crossroads
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
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Tehran, Keshavarz Blv, Ghods street, Central organization of university, Sixth floor
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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
Tehran 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
Tehran university of medical science, Nursing and Midwifery school
Full name of responsible person
Fereshte Gholami Darbarazi
Position
Student of MSc, mail partner of research
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Student of MSc, main partner of research

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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