

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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 sensitivity 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)

Phone

+98 21 6692 7171

Email address

fereshte.gh86@gmail.com

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 gestational 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; normal fetal heart rate and BPP and NST; no sensitivity 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

401/130/92/3

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

questionnaire

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

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran, Keshavarz Blv, Ghods street, Central organization of university, Sixth floor

City

Tehran

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

Other areas of specialty/work

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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