

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect Intrauterin Gel of aqueous extract of Quercus Infectoria gall on the early postpartum hemorrhage

Protocol summary

Study aim

Determining the effect Intrauterin gel of Mazo aqueous extract the early postpartum hemorrhage

Design

Clinical trial with control group, parallel groups, triple blind, randomized, phase 3 on 68 pregnant mothers

Settings and conduct

The present study is a triple blind clinical trial (research unit, researcher, statistical analyst) which is performed on 68 pregnant women eligible for research referred for vaginal delivery to Umm AL- Banin Hospital in Mashhad. In order to blind the gel of Mazo aqueous extract and placebo in a similar applicator, it has been coded by pharmacist consulting professor. Research units are divided into intervention and control groups by purposeful sampling and random allocation. In the intervention and control groups, in addition to routine care, an intrauterine gel applicator of Mazo aqueous extract and placebo is prescribed. Bleeding is measured by weighing disposable Droschit and pads before and after using the drug and at the end of the first, second and fourth hours after delivery.

Participants/Inclusion and exclusion criteria

Conditions included: women who have less than 5 deliveries; age:15 to 44 years old; term pregnancy; body mass index less than 30; fetal weight between 2500-4000. Conditions not included: medical and midwifery problems; water bag ruptured more than 12 hours; maternal temperature more than 38; cesarean section or uterine surgery.

Intervention groups

In the intervention and control groups, in addition to routine care, an intrauterine gel applicator of Mazo aqueous extract and placebo is prescribed.

Main outcome variables

Early postpartum hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210305050583N1**

Registration date: **2021-03-23, 1400/01/03**

Registration timing: **prospective**

Last update: **2021-03-23, 1400/01/03**

Update count: **0**

Registration date

2021-03-23, 1400/01/03

Registrant information

Name

Tayebeh Mollazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

mollazadeht982@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Intrauterin Gel of aqueous extract of Quercus Infectoria gall on the early postpartum hemorrhage

Public title

Evaluation of intrauterine gel of mazo aqueous extract on postpartum hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Persian has informed consent to participate in the study . Tends to have a normal delivery. Have a singleton pregnancy with a display of the peak of the head Maternal body mass index is less than 30 Mathers have no history of anemia HB<7 Has no history of allergies to herbal medicines. Has no history of medical and obstetric diseases. Has no history of cesarean section and uterine surgery. Has a history of giving birth less than 5 times . Gestational age is between 37-42 weeks and in the active phase labore (4-6cm) Fetal weight should be estimated between 2500-4000 Water bag rupture should not be more than 12 hours and temperature should not be more than 38

Exclusion criteria:

Persion dose not want to continue participating in the study. Delivery by cesarean section. Grade 3or 4 perineal rupture or rupture of uterus and cervix occur. Quick deliveries. Have delivery with the device. Have postpartum hemorrhage more than 500cc. Placenta out by hand

Age

From **15 years** old to **44 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling in the maternity ward of Umm AL-Banin Hospital is performed by purposive sampling method based on inclusion and exclusion criteria .Research units are assigned to two groups of intervention and control using random allocation with the sequence created in the randomization website; Mazo and placebo aqueous extract gel has been prepared and packaged in the same way by the pharmacist consulting professor at the Pharmacological Research Center of Medicinal Plants of Mashhad University of Medical Sciences, and the pharmacist consulting professor assigns a code to each group(only the pharmacology consultant is aware).Based on codes A and B assigned to the two groups, the sequence is created AABAB; to hide the allocation, the method of opaque and sealed envelopes, which are numbered in order, will be used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For blinding, aqueous extract gel gel of Mazo and placebo in similar forms and the same applicators are provided to the researcher. Each applicator has a code that only a pharmacist consultant knows. Individuals with inclusion criteria are grouped according to the codes based on the sequence created and until the end of the study, the research unite, researcher, statistical analyst and delivery agent will not know the codes related to aqueous extract of mazo and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Qureshi Building University Street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9173595199

Approval date

2021-03-08, 1399/12/18

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.099

Health conditions studied

1

Description of health condition studied

postpartum hemorrhage

ICD-10 code

O72

ICD-10 code description

Postpartum hemorrhage

Primary outcomes

1

Description

Postpartum hemorrhage

Timepoint

At the beginning of the intervention, at the end of the

first, second, third, fourth and first four hours after delivery.

Method of measurement

By weighing the method of collecting blood bags and disposable drums and pads

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to receiving routine oxytocin, immediately after placenta abruption and uterine massage an interuterine gel applicator containing 700 mg of aqueous extract of mazo is inserted into uterus through the inner hole of cervix.

Category

Prevention

2

Description

Control group:: In addition to receiving routine oxytocin, immediately after placenta abruption and uterine massage an interuterine gel applicatoris containing placebo gel is inserted into uterus through the inner hole of cervix.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Umm AL- Banin Hospital

Full name of responsible person

Dr.Masoumeh Mir Teymouri

Street address

Zarrineh Crossroads, corner of Ayatollah Behjat St.16,
Hazrat Umm AL-Banin Women,s Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

070249278

Phone

+98 51 3223 1601

Fax

+98 51 3223 4441

Email

TeymouriM@mums.ac.ir

Web page address

<https://woman.mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Qureshi Building University St., Vice Chancellor for
Research and Technology, Mashhad University of
Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

917751365

Phone

+98 51 3882 5523

Email

TafaghodiM@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

Tayebeh Mollazadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

University St., PhD. Intersection, Ibn Sina St.,
Mashhad School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code
9137913199
Phone
+98 51 3859 1151
Email
MollazadehT982@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahboubeh Firoozi
Position
Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
University St., Ph.D. Intersection, Ibn Sina St.,
Mashhad School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
FirooziM@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Tayebeh Mollazadeh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work

Midwifery
Street address
University St., Ph. D. Intersection, Ibn Sina St.,
Mashhad School of Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
MollazadehT982@mums.as.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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data will be shared after it becomes unrecognizable

When the data will become available and for how long

6 months after recording the results

To whom data/document is available

Allresearchers

Under which criteria data/document could be used

The reduce postpartum hemorrhage

From where data/document is obtainable

Email: MollazadehT982@mums.ac.ir, Library of Mashhad School of Nursing to Mashhad Daneshgah Street.

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

First, send a requested email and if you do not respond within a week, you can refer to the library of mashhad school of nursing

Comments