

# 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 interaurerine 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 interaurerine 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**

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070249278

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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

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**Phone**

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**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**

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9137913199  
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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  
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## 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**

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**Street address**  
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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