

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of the hydro-alcoholic extract of *Urtica Dioica* on early postpartum hemorrhage

Protocol summary

Study aim

To determine the effect of the hydro-alcoholic extract of *Urtica Dioica* on early postpartum hemorrhage

Design

Three-blind clinical trial with a parallel groups and placebo-controlled, design of 100 patients, randomized

Settings and conduct

The present three-blind clinical trial will conduct on 100 women presenting to Afzalipour Hospital in Kerman. The participants will select and randomly assign into an intervention group (n = 50) and a placebo group (n = 50). The intervention group will be given 10 sublingual drops of the hydroalcoholic extract of *Urtica Dioica* and the control group will be given 10 sublingual drops of the placebo. The amount of bleeding will assess in both groups. The hydro-alcoholic extract and placebo will be labelled A and B by The amount of bleeding was assessed in both groups by the pharmacist, and so both the participants and the researchers will be blinded to the type of treatment administered.

Participants/Inclusion and exclusion criteria

Age between 20 and 35 years Gestational age between 37 and 42 weeks Single fetus with a cephalic presentation and fetal weight between 2500 and 4000 g Clear amniotic fluid less than three pregnancies Known systemic diseases (diabetes, hypothyroidism, and coagulation disorders) History of cesarean section, uterine surgery, or PPH Pregnancy complications (polyhydramnios and gestational bleeding and hypertension) Use of magnesium sulfate during pregnancy Extensive episiotomy in the second stage of labor

Intervention groups

Ten sublingual drops of hydro alcoholic extract of *Urtica Dioica*

Main outcome variables

Postpartum hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160112025983N3**

Registration date: **2019-07-17, 1398/04/26**

Registration timing: **retrospective**

Last update: **2019-07-17, 1398/04/26**

Update count: **0**

Registration date

2019-07-17, 1398/04/26

Registrant information

Name

Hadis Shahrahmani

Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

hadis.rahmani92@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-03, 1397/11/14

Expected recruitment end date

2019-04-03, 1398/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the hydro-alcoholic extract of *Urtica Dioica* on early postpartum hemorrhage

Public title

Effect of *Urtica Dioica* on early postpartum hemorrhage

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20 and 35 years Gestational ages between 37 to 42 weeks Single fetus with a cephalic presentation, fetal weight between 2500 and 4000 g Clear amniotic fluid in the first stage of labor Normal during the first phase less than three pregnancies

Exclusion criteria:

Systemic diseases (diabetes, hypothyroidism, and coagulation disorders) Cesarean section or uterine surgery or postpartum hemorrhage Complications of pregnancy (poly hydramynus, gestational bleeding and hypertension) Use of magnesium sulfate during pregnancy Extensive episiotomy in the second stage of labor

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible participants will be randomly assigned to the *Urtica Dioica* and control groups using simple randomization sequences. Sequential numbered, sealed, opaque envelopes will be used to allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The hydro-alcoholic extract of *Achillea millefolium* and placebo will be labelled A and B by the pharmacist, and so both the participants and the researchers will be blinded to the type of treatment administered. For blinding purposes, all the assessments performed by a person who will be blinded to the type of treatment given to the mothers.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Campus, Haftbagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-12-14, 1397/09/23

Ethics committee reference number

IR.KMU.REC.1397.465

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**

Amount of bleeding

Timepoint

One hour, two hours and three hours after delivery

Method of measurement

Weighing the pads and drapes

Secondary outcomes**1****Description**

Hemoglobin and hematocrit levels

Timepoint

6 hours after delivery

Method of measurement

Blood Test

Intervention groups

1

Description

Intervention group: Ten sublingual drops of hydroalcoholic extract of Urtica Dioica

Category

Treatment - Drugs

2

Description

Control group: Ten sublingual drops of placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Hadis Shahrahmani

Street address

Emam Highway, Afzalipour Hospital, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Hadis Shahrahmani

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable