Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 of100 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 groupsthe pharmacist, and so both the participants and the researchers will 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

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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 performe 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
Hadis Shahrahmani
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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
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Hadis Shahrahmani
Position
Instructor
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Person responsible for updating data

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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