

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of the hydro-alcoholic extract of *Achillea millefolium* on early postpartum hemorrhage

Protocol summary

Study aim

To determine effect of the hydro-alcoholic extract of *Achillea millefolium* on early postpartum hemorrhage

Design

A randomized, triple blind, placebo-controlled clinical trial with a parallel groups design of 100 patients, divide into two groups through random allocation in Excel

Settings and conduct

The present clinical trial conduct on 100 primiparous women presenting to Afzalipour Hospital in Kerman. The intervention group receive ten sublingual drops of hydro alcoholic extract of *Achillea millefolium* plus routine treatment and the control group received ten sublingual drops of the placebo (saline 9.0%) plus routine treatment. Then, all samples assesse until 3 hour after delivery for estimation of postpartum hemorrhage and pulse rate and blood pressure.6 hours after delivery hemoglobin and hematocrite were checked for estimation of postpartum hemorrhage. The hydro-alcoholic extract and placebo labelle A and B by the pharmacist, and so both the participants and the researchers are blinded to the type of treatment administered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 and 35 years old; gestational ages between 37 to 42 weeks; singleton birth with cephalic presentation; child weigh between 2500 to 4000 grams; amniotic fluid is clear on during stages of labor; normal during the first phase the number of pregnancies less than 3. Exclusion criteria: systemic diseases (diabetes, hypothyroidism, coagulation disorders); cesarean section or uterine surgery or postpartum; complications of pregnancy (poly hydramynus, bleeding and hypertension in pregnancy); use the magnesium sulfate during pregnancy; large episiotomy during the second stage of labor.

Intervention groups

Ten sublingual drops of hydro alcoholic extract of *Achillea millefolium*

Main outcome variables

Postpartum hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160112025983N2**

Registration date: **2019-06-22, 1398/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-22, 1398/04/01**

Update count: **0**

Registration date

2019-06-22, 1398/04/01

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

2019-01-20, 1397/10/30

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of the hydro-alcoholic extract of *Achillea millefolium* on early postpartum hemorrhage

Public title
The effect of *Achillea millefolium* on early postpartum hemorrhage

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The age between 20 and 35 years Gestational ages between 37 to 42 weeks Singleton birth with cephalic presentation child weigh between 2500 to 4000 grams Amniotic fluid is clear Normal during the first phase The number of pregnancies less than 3
Exclusion criteria:
 Systemic diseases (diabetes, hypothyroidism, coagulation disorders) Cesarean section or uterine surgery or postpartum Complications of pregnancy (poly hydramynus, bleeding and hypertension in pregnancy) Use the magnesium sulfate during pregnancy Large episiotomy during the second stage of labor

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

Gender
Female

Phase
3

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 subjects divide into two groups through random allocation in Excel

Blinding (investigator's opinion)
Triple blinded

Blinding description
For blinding purposes, all the assessments perform by a person who is blinded to the type of treatment give to the mothers. The hydro-alcoholic extract of *Achillea millefolium* and placebo labelle A and B by the pharmacist, and so both the participants and the researchers are blinded to the type of treatment administered.

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

2019-02-20, 1397/12/01

Ethics committee reference number

IR.KMU.REC.1397.466

Health conditions studied

1

Description of health condition studied

Postpartum hemorrhage

ICD-10 code

O72.1

ICD-10 code description

Postpartum hemorrhage

Primary outcomes

1

Description

Amount of bleeding

Timepoint

One hour, two hours, three hours after delivery

Method of measurement

Weighing pad and drape

Secondary outcomes

1

Description

Hemoglobin and hematocrit level

Timepoint

On admission and 6 hours after delivery

Method of measurement

Blood Test

Intervention groups

1

Description

Intervention group: Ten sublingual drops of hydro alcoholic extract of *Achillea millefolium* (equivalent 10 grams of plant)

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/Deputy of research and technology

Full name of responsible person

Hadis Shahrahmani

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

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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/Deputy of research and technology

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 scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable