

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessing the effect of the hydro alcoholic extract of capsella bursa pastoris on postpartum hemorrhage

Protocol summary

Summary

The aim of this study is to assess the effect of hydro alcoholic extract of Capsella Bursa Pastoris on postpartum hemorrhage done on 100 women in Afzalipour hospital Kerman. This study is a phase 2 clinical trial. The intervention group received ten sublingual drops of hydro alcoholic extract of Capsella Bursa Pastoris(equivalent 10 grams of plant) plus routine treatment (Infusion of 20 units of oxytocin in 1 litter of Ringer) and the control group received ten sublingual drops of the placebo (saline 9.0%) plus routine treatment (Infusion of 20 units of oxytocin in 1 litter of Ringer) after placential expulsion and the subjects were asked to hold drops under the tongue for a minute. Then, all samples were assessed until 3 hour after delivery for estimation of postpartum hemorrhage and pulse rate and blood pressure.6 hours after delivery hemoglobin and hematocrit were checked for estimation of postpartum hemorrhage.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072529066N1**

Registration date: **2016-09-04, 1395/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Sahar Ghalandari

Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti

University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of the hydro alcoholic extract of capsella bursa pastoris on postpartum hemorrhage

Public title

Effect of Capsella Bursa Pastoris on postpartum hemorrhage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The age between 20 and 35 years; the number of pregnancies less than 3; Gestational ages between 37 to 42 weeks; singleton birth with cephalic presentation; child weigh between 2500 to 4000 grams; the lack of systemic diseases (diabetes, hypothyroidism, coagulation disorders); lack of cesarean section or uterine surgery or postpartum hemorrhage; lack of

complications of pregnancy (poly hydramynus, bleeding and hypertension in pregnancy); do not use the magnesium sulfate during pregnancy; amniotic fluid is clear on during the first stage of labor; no large episiotomy during the second stage of labor (rupture of grade 3 or 4); normal during the first phase (Nullipar: 4.6 hours and up to 11.7 hours, multipar: 2.4 hours and up to 5.2 hours), second (nullipar: 50 minutes and multipar: 20 minutes) and third delivery (both 30 minutes); no anemia in the mother. Exclusion criteria: Caesarean section delivery; not interested to continue to participate in the study; causing any sensitivity to the plant capsella bursa pastoris.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Using Exel software, women were randomly allocated to Capsella Bursa Pastoris or control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Velenjak St, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Postal code

1985717443

Approval date

2015-07-13, 1394/04/22

Ethics committee reference number

SBMU2.REC.1394. 16

Health conditions studied

1

Description of health condition studied

Postpartum haemorrhage

ICD-10 code

O72.1

ICD-10 code description

Postpartum haemorrhage

Primary outcomes

1

Description

a mount of bleeding

Timepoint

One hour, two hours, three hours after delivery

Method of measurement

Weighing pad and drape

2

Description

Blood pressure

Timepoint

15 minutes, 30 minutes, 45 minutes, one hour, two hours, three hours after delivery

Method of measurement

by sphygmomanometer

3

Description

Hemoglobin and hematocrit level

Timepoint

on admission and 6 hours after delivery

Method of measurement

Hemoglobin and hematocrit assessment

4

Description

Pulse

Timepoint

15 minutes, 30 minutes, 45 minutes, one hour, two hours, three hours after delivery

Method of measurement

by counting

Secondary outcomes

1

Description

Adverse effects

Timepoint

During Hospitalization

Method of measurement

Observation of adverse effects

2

Description

Satisfaction of Treatment

Timepoint

During Hospitalization

Method of measurement

The questions of participants

Intervention groups

1

Description

Intervention group 1: Ten sublingual drops of hydro alcoholic extract of Capsella Bursa Pastoris(equivalent 10 grams of plant)

Category

Treatment - Drugs

2

Description

Control group:ten sublingual drops of the placebo (saline 0.9 %)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Sahar Ghalandari

Street address

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs Mahrokh Dolatian

Street address

Shahid Beheshti University of Medical Sciences, Velenjak St, Shahid Chamran Highway, Tehran, Iran

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Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery of Shahid Beheshti

Full name of responsible person

Sahar Ghalandari

Position

Master of Science University Student of Midwifery

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty