# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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 placental 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

**Country**

Iran (Islamic Republic of)

**Phone**

+98 34 3322 7641

**Email address**

sahar@sbmu.ac.ir

**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 (Nulipar: 4.6 hours and up to11.7 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 sofware, women were randomally 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 presure

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

**Method of measurement**
by sphygnomanometer

**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
**City**
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**
**Street address**
School of Nursing and Midwifery, Valiasr Ave, Niayesh Highway, Tehran, Iran
**City**
Tehran
**Postal code**
1985717443
**Phone**
+98 21 8865 5366
**Fax**
+98 21 8820 2521
**Email**
sghalandari68@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
School of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Nourossadat Kariman
**Position**
Assistant Professor, PhD of Reproductive Health
**Other areas of specialty/work**
**Street address**
School of Nursing and Midwifery, Valiasr Ave, Niayesh Highway, Tehran, Iran
**City**
Tehran
**Postal code**
1985717443
**Phone**
+98 21 8865 5366

**Fax**
+98 21 8820 2521
**Email**
n_kariman@sbmu.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
School of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Sahar Ghalandari
**Position**
Master of Science University Student of Midwifery
**Other areas of specialty/work**
**Street address**
School of Nursing and Midwifery, Valiasr Ave, Niayesh Highway, Tehran, Iran
**City**
Tehran
**Postal code**
**Phone**
+98 21 23871
**Fax**
-
**Email**
sghalandari68@gmail.com
**Web page address**

## 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*