Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effect of extracts of the date, dill and grape seed versus placebo on postpartum hemorrhage in fourth stage of labor: a double-blind randomized clinical trial

Protocol summary

Study aim
To compare the effect of extracts of the date, dill and grape seed versus placebo on postpartum hemorrhage in fourth stage of labor

Design
This is a double-blind randomized clinical trial, in which 200 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible pregnant women for normal delivery who will refer to Fatemieh Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 40 years Normal body mass index, Gestational age between 37 to 41 weeks, Normal childbirth, Second pregnancy without the need for episiotomy, Normal length of the first, second and third stages of delivery, Abnormal bleeding Exclusion criteria: Any complications of pregnancy, Fetal weight between 2500 and 4000 grams, Cephalic presentation, Chronic diseases such as cardiopulmonary, kidney, diabetes, or thalassemia

Intervention groups
Intervention group 1: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing 70% date extract Intervention group 2: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing 70% dill extract Intervention group 3: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing 70% grape seed extract Control group: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing placebo

Main outcome variables
Primary outcome: Hemorrhage in the fourth stage of labor

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N300**
Registration date: **2019-09-24, 1398/07/02**
Registration timing: **prospective**

Last update: **2019-09-24, 1398/07/02**
Update count: **0**

Registration date
2019-09-24, 1398/07/02

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-12, 1398/07/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of extracts of the date, dill and grape seed versus placebo on postpartum hemorrhage in fourth stage of labor: a double-blind randomized clinical trial

Public title

Comparison of the effect of extracts of the date, dill and grape seed versus placebo on postpartum hemorrhage in fourth stage of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years Normal body mass index, Gestational age between 37 to 41 weeks, Normal childbirth, Second pregnancy without the need for episiotomy, Normal length of the first, second and third stages of delivery, Abnormal bleeding

Exclusion criteria:

Any complications of pregnancy, Fetal weight between 2500 and 4000 grams, Cephalic presentation, Chronic diseases such as cardiopulmonary, kidney, diabetes, or thalassemia

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare eight sheets of paper, writing on two sheets the name of the intervention 1, on two other sheets the name of the intervention 2, on two other sheets the name of the intervention 3 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The eight paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-09-14, 1398/06/23

Ethics committee reference number

IR.UMSHA.REC.1398.475

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

Hemorrhage in the fourth stage of labor

Timepoint

One and two hours after the intervention

Method of measurement

By physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing 70% date extract
Category
Treatment - Other

2

Description
Intervention group 2: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing 70% dill extract
Category
Treatment - Other

3

Description
Intervention group 3: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing 70% grape seed extract
Category
Treatment - Other

4

Description
Control group: Infusion of oxytocin 300 U in 500 ml Ringer's serum plus lavage with warm water containing placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan City
Full name of responsible person
Arezoo Shayan
Street address
Fatemieh Hospital, Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Arezoo Shayan
Position
Master of Midwifery
Latest degree
Master
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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