An Investigation into Effectiveness of grape powder on volume of Postpartum Hemorrhage

Protocol summary

Summary
This clinical trial by aim of evaluating the effect of Grape core powder on decreasing the postpartum hemorrhage carried out on 120 normal pregnant mothers at term, which hospitalized on Vali-eh-Asr hospital in Birjand. Intervention on four groups carried out after exit of Placenta. In control group, infusion of 20 unit Oxytocin in 1000 CC serum of 5% Dextrose and 0.9% Sodium chloride with speed of two CC/min carried out; and Placebo capsules, which filled with Starch powder with one-half glass of water, offered to mother and asked her to drink it in one minute. In second group, in addition to the above items, a 50-milligram capsule of Grape seed powder offered. In third group in addition to the above items, a 100-milligram capsule of Grape seed powder offered. Group four in addition to the above items a 150-milligram capsule of Grape seed powder offered. Group four in addition to the above items a 50-milligram capsule of Grape seed powder offered. Then a buttocks with plastic cover and specified weight spread under mother and a pad on Perineum of mother used for collecting the excreted blood. All of buttocks and Pads using a digital balance with 5-gram precision weighted before and after of use; and for evaluating the volume of bleeding, their weight differences up to 24 hours after exit of Placenta calculated and every gram increase in weight assumed as one CC blood. Hemoglobin and Hematocrit tests carried out before and after of childbirth to evaluate the volume of bleeding. Main outcome variable: decrease in postpartum hemorrhage.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2014010616097N1
Registration date: 2014-05-30, 1393/03/09
Registration timing: retrospective

Scientific title
An Investigation into Effectiveness of grape powder on volume of Postpartum Hemorrhage

Public title
The effect of grape seed powder of postpartum hemorrhage

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria included: Consent have inclusion, Age between 18 to 35 year, Gravid less than 3, Term pregnancy, Live fetus, Weight 2500-4000 gm, Normal volume of amniotic fluid, Having a history of bleeding before delivery, No history of previous postpartum hemorrhage, Normal during the second and third stage of labor, Lack of labor, No quick delivery, No history of medical conditions, The lack of any kind of development cesarean surgery on the uterus, Singleton pregnancy, Normal vaginal delivery without the use of a vacuum, Absence of four fourth degree laceration, Retained placenta and episiotomy, Breast feeding is less than 1 hour after birth, Not taking anticoagulants, Addict being the mother, Having diabetes, Having a high BMI, Not fat and 

Exclusion criteria included: Bleeding before delivery, Start breastfeeding for more than 1 hour after birth, History of previous cesarean section, Blood pressure greater than or equal to 140/90 mm Hg, Hemoglobin less than 8 g per deciliter, Placenta previa, Allergy to foods such as grapes.

Age
From 18 years old to 35 years old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 120

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Birjand University of Medical Sciences

Street address
Ghaffari Street

City
Birjand

Postal code
9817938453

Approval date
2013-12-15, 1392/09/24

Ethics committee reference number

Health conditions studied

1
Description of health condition studied
Postpartum hemorrhage

ICD-10 code
072

ICD-10 code description
Haemorrhage following delivery of placenta

Primary outcomes

1
Description
Postpartum Hemorrhage

Timepoint
1, 2, 24 hours after delivery

Method of measurement
weight buttocks and Pad by Iranian digital scale

Secondary outcomes

1
Description
Hemoglobin

Timepoint
24 hours after birth

Method of measurement
Blood sampling

Intervention groups

1
Description
Immediately after the expulsion of the placenta, control group, 20 IU oxytocin infusion in 5% dextrose and sodium chloride thousand milliliter of sodium chloride and 0/9% speed was 2 ml per minute

Category
Treatment - Drugs

2
Description
Immediately after the expulsion of the placenta, the second infusion of 20 IU oxytocin in thousands milliliter of 5% dextrose and chloride Sdybm 0/9% rate of 2 ml per minute plus 50 mg Pvdhrsth grapes in 50 cc of warm water mixed with

Category
Treatment - Drugs

3
Description
Immediately after the expulsion of the placenta, the third group, the infusion of 20 IU oxytocin in thousands milliliter of 5% dextrose and sodium chloride 0/9% rate of 2 ml per minute plus 100 mg Pvdrhsth grapes in 50 cc of warm water mixed with

Category
Treatment - Drugs

Description
Immediately after placenta, Group IV infusion of 20 IU oxytocin in thousands milliliter of 5% dextrose and sodium chloride 0/9% rate of 2 ml per minute plus 150 mg Pvdrhsth grapes in 50 ml of warm water mixed with

Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Asr Hospital
Full name of responsible person
Ali Mohammad izadpanah
Street address
School of Nursing & Midwifery Ghaffari Street
City
Birjand

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Ali Mohammad Izadpanah
Street address
Ghaffari Street
City
Birjand
Grant name
2
Grant code / Reference number
929
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Elham Alahyari
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Person responsible for scientific inquiries

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Ali Mohammad Izadpanah
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Person responsible for updating data

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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