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 150-milligram capsule of Grape seed powder offered. Then a buttocks with plastic cover and specified weight spread under mother and a pad on Perinea 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

Last update:
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**
Name of ethics committee
Birjand University of Medical Sciences

Street address
Ghaffari Street

City
Birjand

Postal code
9817938453

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

**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 5dybm 0/9% rate of 2 ml per minute plus 50 mg Pvdhrst 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 Pvdhrsth grapes in 50 cc of
warm water mixed with

Category
Treatment - Drugs

4
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 Pvdhrsth 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
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
Position
Nursing Graduate Student
Other areas of specialty/work
Street address
Ghaffari Street
City
Birjand
Postal code
971785357
Phone
+98 56 1444 3041
Fax
+98 56 1444 0556
Email
elhamalabayari@bums.ac.ir
Web page address
www.bums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Ali Mohammad Izadpanah
Position
Faculty member
Other areas of specialty/work
Street address
Ghaffari Street
City
Birjand
Postal code
971785357
Phone
+98 56 1444 3041
Fax
+98 56 1444 0556
Email
izadpanahy@bums.ac.ir
Web page address
www.bums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Elham Alahyari
Position
Nursing Graduate Student

Other areas of specialty/work

Street address
frkhy Sistani Zybashhr

City
Zahedan

Postal code
9817938453

Phone
+98 54 1341 2129

Fax
+98 65 1443 0076

Email
elhamalahyari@bums.ac.ir

Web page address
www.bums.ac.ir

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