# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Nov 2026

## Survey of the effect of date fruit consumption on amount of postpartum hemorrhage in women hospitalized.

## Protocol summary

**Study aim**
The aim of this study is to determine the effect of date fruit consumption on amount of postpartum hemorrhage.
**Design**
Clinical trial with a control and randomized parallel group design without blinding, will be performed on 98 people.Randomization list from the online randomization service Sealed Envelope Ltd. 2019 will be used.
**Settings and conduct**
This study will be performed in the labour and postpartum ward of Al-Zahrah Educational, Research and Remedial Center in Rasht, affiliated to Guilan University of Medical Sciences. Intervention, consume 100 gr of dates will be performed on the intervention group. There is no intervention in the control group. Both groups will receive routine postpartum care. This study is not blinding.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: age between 18 and 35 years; BMI between 18/5 to 29/9 kg/m2; no existence and history of medical disorders and pregnancy complications; estimated fetal weight between 2500 to 4500 gr; term and singleton pregnancy; normal amniotic fluid index. Exclusion criteria: rupture of embryonic membranes more than 12 hours; precipitous delivery; operative delivery; grade 3 or 4 tear; retention of placenta; severe bleeding in fourth stage of birth; receive oxytocin more than routine dosage of hospital.
**Intervention groups**
Intervention group: Two hours after delivery and stability of the samples 100 gr of Bam mazafati dates which are weighed and packaged by the researcher, should be given to them to eat within a maximum time of 2 hours. A pack of sanitary pads and Pictorial Blood loss Assessment Chart (PBAC) will be given to them. PBAC should be completed within first 24 hours after delivery based on amount of bleeding. Control group: In this group, only routine care will be performed. Also a package of sanitary pads and PBAC will be given to them.
**Main outcome variables**
Amount of postpartum hemorrhage

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20210607051505N2**
Registration date: **2021-10-31, 1400/08/09**
Registration timing: **prospective**

Last update: **2021-10-31, 1400/08/09**
Update count: **0**
**Registration date**
2021-10-31, 1400/08/09

**Registrant information**
**Name**
maryam niknami
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 13 3355 5056
**Email address**
niknami@gums.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2021-11-11, 1400/08/20
**Expected recruitment end date**
2022-04-09, 1401/01/20
**Actual recruitment start date**
empty
**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Survey of the effect of date fruit consumption on amount of postpartum hemorrhage in women hospitalized.

**Public title**

Survey of the effect of date fruit consumption on amount of postpartum hemorrhage.

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 18 and 35 years Having minimum of primary education History of childbirth less than 5 times ( not being grandmultipara) Body Mass Index (BMI) between 18/5 to 29/9 kg/m2 Lack of history and absence of medical disorders and pregnancy complications Not receiving herbal remedies during pregnancy Estimated fetal weight between 2500 to 4500 gr Term and singleton pregnancy Vertex presentation Normal amniotic fluid index in third trimester sonography Normal length of the first, second and third stages based on birth partograph Breastfeeding begins less than two hours after delivery

**Exclusion criteria:**

Rupture of embryonic membranes more than 12 hours Precipitous delivery Operative delivery Grade 3 or 4 tear Retention of placenta Remove placenta with courage Severe bleeding in fourth stage of birth Receive oxytocin more than routine dosage of hospital

**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: **98**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The type of randomization is blocking and will be divided into two groups of date consumer and control using the block randomization method with the size of 4 and 6 blocks. The method used to generate the random allocation sequence is from the online randomization service Sealed Envelope Ltd. 2019 will be used (https://www.sealedenvelope.com/simple-randomiser/v1/lists). The method of concealing the allocation is to use sealed envelopes.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Guilan University of Medical Sciences

**Street address**

Daneshjoo St, Rasht - Shahid Beheshti Highway, Rasht Town

**City**

Rasht

**Province**

Guilan

**Postal code**

39841-41469

**Approval date**

2021-09-29, 1400/07/07

**Ethics committee reference number**

IR.GUMS.REC.1400.309

## Health conditions studied

### 1

**Description of health condition studied**

Postpartum hemorrhage

**ICD-10 code**

O72.1

**ICD-10 code description**

Other immediate postpartum haemorrhage

## Primary outcomes

### 1

**Description**

Postpartum hemorrhage scores within first 24 hours ( primary Postpartum hemorrhage) in pictorial blood loss assessment chart

**Timepoint**

First 24 hours after intervention

**Method of measurement**

The method of measuring the Postpartum hemorrhage is the standard pictorial blood loss assessment chart. This tool is a table that shows the days of bleeding in horizontal and bloodstain pads or tampons or clots in vertical rows. Bloody pads or tampons divide to three degrees: mild with 1 score, moderate with 5 score and severe with 20 score. Small and large clots gain 1 and 5 scores, respectively. Women mark table after changing their pads every time within 24 hours after birth. At the end of 24 hours the final scores will be calculated. The cut-off score of severe bleeding is 100 and more. The validity and reliability of PBAC have been proven in

numerous studies.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Two hours after delivery and stability of the samples 100 gr of Bam Mazafati dates which are weighed and packaged by the researcher, should be given to them to eat within a maximum time of 2 hours. A pack of sanitary pads will be given. Pictorial Blood loss Assessment Chart (PBAC) will be given to them and it should be completed within first 24 hours after delivery based on amount of bleeding.
**Category**
Prevention

### 2

**Description**
Control group: In this group, only routine care will be performed. Also a package of sanitary pads and PBAC will be given to them
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Alzahra Educational,Research and, Remedial Center
**Full name of responsible person**
Maryam Niknamy
**Street address**
Namjoo St, Rasht Town
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**Province**
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niknami@gums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice Chancellor of Guilan University of Medical Sciences
**Full name of responsible person**
Mohammad Reza Naghipour
**Street address**
Daneshjoo St, Rasht - Shahid Beheshti Highway, Rasht Town
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naghi@gums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice Chancellor of Guilan 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**
Rasht University of Medical Sciences
**Full name of responsible person**
Maryam Farash
**Position**
Master student of midwifery
**Latest degree**
Bachelor
**Other areas of specialty/work**
Midwifery
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## Person responsible for scientific inquiries

**Contact**

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Faculty Member (Instructor)

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Master

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Midwifery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Rasht University of Medical Sciences

**Full name of responsible person**
Maryam Farash

**Position**
Master student of midwifery

**Latest degree**
Bachelor

**Other areas of specialty/work**
Midwifery

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**Email**
farimah.farash98@gmail.com

## 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