Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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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Daneshjoo St., Rasht - Shahid Beheshti Highway, Rasht Town

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Maryam Niknami

Position
Faculty Member (Instructor)

Latest degree
Master

Other areas of specialty/work
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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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