# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of plantago major cream on perineal pain and episiotomy wound healing at primeval women

## Protocol summary

**Study aim**
Determination of the Effect of plantago major cream on perineal pain and episiotomy wound healing at primeval women

**Design**
The study will include two groups of medicines for120 eligible women

**Settings and conduct**
Drug and drug coding will be done by the pharmacist.the study will take place within 10 days and will be completed within 14days.Research units of prenatal women are referred to the hospital

**Participants/Inclusion and exclusion criteria**
Primeval, Reading and writing literacy, 18-35 year, Not having genital disease, lack of cesarean section, No pelvic tightness, Active phase when admitted, BMI:19/8-29, No having vaginal problems,no use of effectivr drug for episiotomy ulcer repair during the study; Childbirth with the device, Curettage, Repture grades 3 and 4 , Hematoma at the suture site, Mathers transfer to the operating room, Unblocking stitches, Vaginal infection, Cervical rupture, Consumption of creem unlike ordar, The baby is admitted to the nicu

**Intervention groups**
In the group and placebo, daily intake of bacon will be done and both will carry out routine care at the hospital

**Main outcome variables**
Prineal pain and episiotomy wound healing

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180729040631N1**
Registration date: **2018-09-13, 1397/06/22**
Registration timing: **prospective**
Last update: **2018-09-13, 1397/06/22**
Update count: **0**

**Registration date**
2018-09-13, 1397/06/22

**Registrant information**

**Name**
Bahare Baghal

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 56 3245 0316

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baghalb951@mums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-09-23, 1397/07/01

**Expected recruitment end date**
2019-01-20, 1397/10/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effect of plantago major cream on perineal pain and episiotomy wound healing at primeval women

**Public title**
Effect of plantago major cream on perineal pain and episiotomy wound healing

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Primeval Reading and writing literacy 18_35 year Not having genital disease Lack of cesarean section No pelvic tightness Active phase when admitted BMI:19/8-29 No having vaginal problems No use of effective drug for episiotomy ulcer repair during the study

**Exclusion criteria:**

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples were selected by convenient metod. The code A and B , one for the drug and the other for the placebo, is placed in a container and allocated to the research units, respectively.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The same packaging and drug coding will be done by the pharmacist.The investingator and the research unit and the person who imprts the statistical data do not know the drug and the prescriber.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

The Ethics committee of the Mashhad Medical science University

**Street address**

University street, Quraishi Building

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91735-951

**Approval date**

2018-07-29, 1397/05/07

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1397.013

## Health conditions studied

### 1

**Description of health condition studied**

Perineal pain and episiotomy wound healing

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Perineal pain and episiotomy wound healing

**Timepoint**

14 day

**Method of measurement**

Reeda Questionnaire and McGill pain Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Daily intake twice creem

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Valiasr hospital

**Full name of responsible person**

Nahid ghanbarzadeh

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Ghaffari street

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
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Rahele babazadeh
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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**
Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Bahare Baghal
**Position**
Senior midwifery student
**Latest degree**
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**Other areas of specialty/work**
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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