

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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 for 120 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 14 days. 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 effective 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 cream 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

Perineal 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

Email address

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 method. 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 investigator and the research unit and the person who inputs 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 cream

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Nahid ghanbarzadeh

Street address

Ghaffari street

City

Birjand

Province

South Khorasan

Postal code

9177116763

Phone

+98 56 3244 3000

Email

Nghanbarzadeh@gmail.com

Sponsors / Funding sources

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Rahele babazadeh

Street address

University of nersing, Faculty nersing and midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9913197319

Phone

+98 51 3859 1511

Email

Babazadehr@mums.ac.ir

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

Master

Other areas of specialty/work

Midwifery

Street address

University of nersing, Faculty of nersing snd midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9177116763

Phone

+98 56 3245 0316

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Rahele Babazade

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

University of nersing , Faculty of nersing and midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

Babazadehr@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Bahare Baghal

Position

Senior midwifery student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

University of Nursing , Faculty of Nersing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9177116763

Phone

+98 56 3245 0316

Email

Baghalb951@mums.ac.ir

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