Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of the ointment of Sesamum on the intensity of episiotomy pain and wound healing

Protocol summary

Study aim

evaluate the effect of sesame ointment on pain intensity of episiotomy and wound healing

Design

the study population consisted of women admitted to Akbar Abadi maternity hospital admitted for normal birth.The research sample consisted of 104 primiparous women who were randomly assigned to quadruple blocks.

Settings and conduct

Evaluation of healing of episiotomy and pain intensity before,7 and 10 days after intervention was done by a trained researcher and recorded in the form of healing wound of REEDA and pain form VAS.Ointments are packed in the same color and aroma with the same codes as A,B and will be placed on samples according to the letters inserted in the form of the drug form.

Participants/Inclusion and exclusion criteria

Age18-35؛gestational age42-37weeks؛lack of addiction and psychotropic drug؛single cephalic fetus؛no history of damage or previous surgery and visible lesions in the perineum؛lack of rectocele and severe cystosclerosis grade 2؛anesthesia with lidocaine1%؛episiotomy incision45°and medial؛lack of vaginal symptom inflammation؛having BMI lower than 30؛no coagulation؛connective tissue disorders؛diabetes؛Anemia؛immune deficiency؛malnutrition؛no amniotic rupture for more than 24 hours؛lack of long or fast delivery؛having separate sutures restored with CutCuteCotton.fever؛hemmatoma؛abnormal vaginal bleeding؛Postpartum curettage

Intervention groups

intervention group(sesame ointment)and control group(placebo) use ointments every 8 hours for10days.

Main outcome variables

pain intensity is different before and 7 days after treatment with sesame ointment and placebo;pain intensity7 and 10 days after treatment with sesame ointment and placebo;the wound healing before and 7 days after treatment s different from treatment with sesame ointment in placebo;The wound healing of episiotomy 7 and10 days is different from treatment with sesame ointment in placebo.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170112031902N2**
Registration date: **2018-04-09, 1397/01/20**
Registration timing: **retrospective**

Last update: **2018-04-09, 1397/01/20**
Update count: **0**

Registration date

2018-04-09, 1397/01/20

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 91208360111

Email address

najmeseven@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the ointment of Sesamum on the intensity of episiotomy pain and wound healing

Public title
The effect of the ointment of Sesamum on the episiotomy wound
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 35 years old gestational age of 42-37 weeks lack of susceptibility to certain drugs in the past living with a spouse llack of addiction and psychotropic drugs lack of history of hepatocellular disorders single fetus with cephalic presentation no history of damage Or previous surgery and visible lesions in the perineum lack of rectocele and severe cystosclerosis grade 2 and upper wall or mass in the vaginaperineal anesthesia with lidocaine 1% perineal anesthesia with lidocaine 1% episiotomy incision 45 ° and medial lateral lack of vaginal symptom inflammation At the onset of the study having no BMI greater than 30 no coagulation and connective tissue disorders, diabetes Anemia, immune deficiency, malnutrition no amniotic rupture for more than 24 hours lack of long or fast delivery having separate sutures that have been restored with Cut Cute Cotton.
Exclusion criteria:
presence of a fever Hematoma formation Perform curettage action Abnormal vaginal bleeding
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
By random allocation method, blocked in one of the intervention and control groups by random block method with two patients.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to blind the study, the research and statistical analysis group and mothers will not be aware of the type of ointment used.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethicts committee of Iran University of Medical Sciences
Street address
Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2017-12-03, 1396/09/12
Ethics committee reference number
IR.IUMS.REC 1396.9311373003

Health conditions studied

1

Description of health condition studied
episiotomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of pain in episiotomy
Timepoint
Before, 7 and 10 days after intervention
Method of measurement
Visual Analog Scale (VAS)

2

Description
Healing episiotomy
Timepoint
Before, 7 and 10 days after intervention
Method of measurement
REEDA tool

Secondary outcomes

empty

Intervention groups

1

Description
In this study, the sesame oil ointment brand Burnagol, a pharmaceutical company of Gol-Dara, was approved by the Food and Drug Administration of Iran, with beta-cytosterol at 0.25% as the main ingredient in the trace element of sesame oil. Four hours after episiotomy repair, use a cuff (equivalent to 25 mg) of ointmenton episiotomy location every 8 hours for ten days.
Category
Treatment - Drugs

2

Description
Control group: In this study, the placebo ointment in Shahid Beheshti Pharmaceutical Faculty was created at the faculty laboratory with the same amount, shape, odor, color and tube similar to the intervention drug, the main basis of which is vaseline (other materials are neutral compounds). It should be noted that the base of each ointment is one, so there is no need for another control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Abadi Hospital
Full name of responsible person
Najme Amani Babadi
Street address
Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
najmeseven@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Masoome Kheirkhah
Street address
Valis Asr Street, Above Vanak Square, Rashidiassemi Avenue, Iran Nursing and Midwifery Faculty
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
najmeseven@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Najme Amani Babadi
Position
Student of Master of Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Valis Asr Street, Above Vanak Square, Rashidiassemi Avenue, Iran Nursing and Midwifery Faculty
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 0000
Fax
Email
najmeseven@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr Masoome Kheirkhah

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
midwifery

Street address
Tehran, Valiasr St., above Vanak Square, Rashidiassemi Avenue, Iran Nursing and Midwifery Faculty

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 0000

Fax

Email
shivakheirkhah1345@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Najme Amani Babadi

Position
student of master of midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Tehran, Valiasr St., above Vanak Square, Rashidiassemi Avenue, Iran Nursing and Midwifery Faculty

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 0000

Fax

Email
najmeseven@gmail.com

Web page address

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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Potential data can be shared after unidentifiable people

When the data will become available and for how long
The start of the access period is 6 months after the results are printed

To whom data/document is available
Data will only be available to researchers in academia and academia

Under which criteria data/document could be used
I do not have any plans yet

From where data/document is obtainable
Najme Amani Babadi Faculty of Nursing and Midwifery, Iran University of Medical Sciences Phone Call email: najmeseven@gmail.com

What processes are involved for a request to access data/document
A week after sending or sending an email, information is sent.

Comments