Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating The Effect Of Olea Ointment On Cesarean Incision Local Pain And Healing In Mothers After Cesarian Cection

Protocol summary

Study aim
Determination Of Investigating The Effect Of Olea Ointment On Cesarean Incision Local Pain And Healing In Mothers After Cesarian Section

Design
Randomised,Controlled, Parallel Group Trial, Double Blinded Design Of 92 Patients. Randomisation Was Done By Online Randomization Service Point Sealed Envelope Ltd2019

Settings and conduct
Eligible Mothers Are In Two Groups Of Olea And Placebo Ointment And Receive Olea And Placebo Ointment Every 12 Hours And The Amount Of Pain And Repair Of Their Abdominal Incision Will Be Measured With Pain And Rida Instruments.

Participants/Inclusion and exclusion criteria
Willingness And Satisfaction To Enter The Study, Cesarean Delivery In Al-Zahra Educational-Medical Center In Rasht and Shahid Hosseinpour Langroud Hospital, Primary And Multi-par Mothers With a History Of Two Cesarean Sections, Gestational Age 37 to 42 Weeks Depending On The Ultrasound Or The First Day of The Last Period, Abdominal Incision Of Transverse Type, Maximum Rupture Time Of Membran Less Than 12 Hours, Minimum Literacy, Have a phone number, Absence of systemic diseases including Diabetes And Cardiovascular Disease, Blood Pressure Coagulation Disorders During Or Before Pregnancy, No Postpartum Hemorrhage, No Blood Transfusion In Surgery, Do Not Take Certain Medications That Increase The Risk Of Postpartum Infection. Misuse Of Olea Ointment By Research Units, Allergy To Ointment During the Study, Concomitant Use Of Other Ointments Or Topical Medications

Intervention groups
The Intervention Group Applied Olea Ointment To The Cesarean Section Every 12 hours. After At Least Two Minutes, Covered The Wound With A Sterile Gauze And Bandaged It. The First Intervention Will Be Performed 24 Hours After The Operation.

Main outcome variables
Rate Of Local Pain, Abdominal Incision Repair

General information

Reason for update
Added research environment

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20170203032374N3**
Registration date: **2021-10-10, 1400/07/18**
Registration timing: **prospective**

Last update: **2022-02-05, 1400/11/16**
Update count: **1**

Registration date
2021-10-10, 1400/07/18

Registrant information

Name
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Name of organization / entity
Guilan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating The Effect Of Olea Ointment On Cesarean Incision Local Pain And Healing In Mothers After Cesarian Cection

Public title
Investigating The Effect Of Olea Ointment On Cesarean Incision Local Pain And Healing In Mothers After Cesarian Cection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness And Satisfaction To Enter The Study Cesarean Delivery In Al-Zahra Educational-Medical Center In Rasht and Langroud Shahid Hosseinpour Hospital Primary And Multi-par Mothers With A History Of Two Cesarean Sections Gestational Age 37 to 42 Weeks Depending On The Ultrasound Or The First Day Of The Last Period Abdominal Incision Of Transverse Type Maximum Rupture Time Of Membran Less Than 12 Hours Minimum Literacy, Have A phone number To follow Absence Of Systemic Diseases Including Diabetes And Cardiovascular Disease Blood Pressure Coagulation Disorders During Or Before Pregnancy No Postpartum Hemorrhage No Blood Transfusion In Surgery Do Not Take Certain Medications That Increase The Risk Of Postpartum Infection
Exclusion criteria:
Misuse Of Olea Ointment By Research Units Allergy To Ointment During the Study Concomitant Use Of Other Ointments Or Topical Medications
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
In This Study, By The Number Of Sample Volumes Required, Block Randomization With 4 And 6 Block Sizes Will Be Used To Randomize Sample In The Two Groups Of Olea Ointment And Placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
The Present Study Will Be a Double-Blind, Randomized, Placebo-Controlled Clinical Trial. The Researcher And Research Units Will Be Unaware Of The Content Of Ointments Used. A Person Outside The Group Will Know The Content Of Ointments Used And Will Classify The Ointments According To A And B, Which Represent (Intervention And Placebo Group) And According To The Pre-Determined Random List, It Will Be Labeled On Ointments A And B And Packed In A Non-Transparent Envelope In The Order And Sequence, And Will Be Provided To The Researcher Inside The Box. Then, If They Are Satisfied, They Will Be Selected To Participate In The Study In An Accessible And Gradual Manner, And All Eligible Individuals Will Be Divided Into Two Groups Of Olea Ointment And Placebo According To The Specified Sequence, Using A Block Randomization Method With 4 And 6 Block Sizes. The Contents Of The Ointments Will Be Provided To The Research Units In Clean Containers Of One Shape and One Color And Free Of Charge.
Placebo
Used
Assignment
Parallel
Other design features
Not

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Deputy of Research and Technology of Gilan University of Medical Sciences, in front of 17 Shahrivar Hospital, Shahid Siadati Ave., Namjoo St.
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Postal code
41446-66949
Approval date
2021-09-29, 1400/07/07
Ethics committee reference number
IR.GUMS.REC.1400.306

Health conditions studied

1

Description of health condition studied
The Extent of Local Pain and Repair of Cesarean Section in Referring Mothers
ICD-10 code

090.0

ICD-10 code description

• O85-O92 Complications Predominantly Related To the PuerperiumO86.0 Infection of Obstetric Surgical Wound. Infected Caesarean Section Wound Followimg Delivery

Primary outcomes

1

Description

The Extent of Local Pain and Repair of Cesarean Section in The Referring Mothers

Timepoint

The Severity of Pain Before With the Visual Scale of Pain Ruler and The Condition of Abdominal Incision Improvement Are Also Evaluated And Recorded By The Researcher Using The Reeda Scale Before The Intervention, 24 Hours After The First Intervention And On Days 5 And 10 After Cesarean Section.

Method of measurement

Visual Analogue Scale (VAS) and Reeda

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Intervention Group Will Be The Group Receiving Olea Ointment. First, The Researcher Will Be Taught How To Use The Ointment For The First Time, And Then The Samples Of The Intervention Group Will Be Asked To Place A Layer Of Olea Ointment On The Abdominal Cesarean Section Every 12 Hours And For At Least Two Minutes. Remain On The Skin And Then Cover The Wound With Sterile Gauze And Bandage. The First Intervention Will Be Performed By The Researcher 24 Hours After The Operation And The Next Interventions Will Be Performed By The Researcher During The Hospital Stay and After Discharging The Samples From The Hospital. It Will Be Done By The Person Himself

Category

Treatment - Drugs

2

Description

Control group: The Placebo Group Will Receive A Placebo Ointment. First, The Researcher Is Taught How To Use The Ointment For The First Time, And Then The Samples Of The Intervention Group Are Asked To Put A Layer Of Ointment On The Abdominal Cesarean Section Every 12 Hours And On The Cesarean Section For At Least Two Minutes. The Skin Remains And Then The Wound Is Covered With Sterile Gauze AndThe First Intervention Will Be Performed By The Researcher 24 Hours After The Operation And The Next Interventions Will Be Performed By The Researcher During The Hospital Stay And After Discharge Of The Samples From The Hospital By The Person Will Do It Himself.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra educational, research, and remedial center

Full name of responsible person

Fatemeh Jafarzadeh kenarsari

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Guilan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice Chancellor for Research and Technology of Guilan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Nursing and Midwifery School of Shahid Dr. Beheshti
Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The results of the data and the main consequences will be shared after the study in format of knowledge translation and exchange report to the university, presentation of reports in domestic or foreign conferences and seminars and publication of article in domestic or foreign scientific-research journals
When the data will become available and for how long
It is possible to access the study results after the defense and scientific confirmation of the dissertation In a 3 months period
To whom data/document is available
if requested, results will be available to other academic investigators and Vice Chancellor for Research and Technology of Guilan University of Medical Sciences
Under which criteria data/document could be used
The collected data is confidential and will not be disclosed to other persons without the awareness of the Vice Chancellor for Research and Technology of the relevant university
From where data/document is obtainable
To receive the documentation, send the email for update manager
What processes are involved for a request to access data/document
After the necessary checks, the desired documentary will be sent by email within one month period
Comments