Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of grape seed ointment (Vitis Vinifera) on women cesarean wound healing

Protocol summary

Summary

The study aims to determine the effect of grape seed ointment on cesarean wound healing. In this doubeel blind randomized controlled clinical trial , women between 18-35 years of age with a gestational age of 37-42 weeks that are not allergic to grape seed ointment will be selected for the study ,and will be excluded if they do not use ointment regularly and as directed. The study will be conducted on 129 women referring to Vali-asr Hospital in Birjand for caesarian surgery who will be randomly assigned to three groups of grape seed ointment 5%, grape seed ointment 2.5% and placebo. A coded package of ointment will be given to the mothers, and they will be trained on how to use it; that is,having washed their hands thouroughly and while wearing disposable gloves, they are expected to rub the ointment as much as the tip of a finger on the stitched area and repeat the steps twice a day (12 hours ± 2) from the second day after the operation to the fifteenth day .Health care points will be taught to all mothers .on the fifth and twelfth days after cesarean section,the researcher will do the follow-up by phone.Cesarean wound healing will be measured by REEDA scale. in three stages: the second day after surgery, before treatment with ointments, eighth and sixteenth days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122220393N1**
Registration date: **2015-02-16, 1393/11/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-02-16, 1393/11/27

Registrant information

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Name of organization / entity
Birjand University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Making ointments 2.5 and 5% of grape seed and placebo ointment will be made by the pharmaceutical industry complex Dineh

Expected recruitment start date

2015-04-20, 1394/01/31

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of grape seed ointment (Vitis Vinifera) on women cesarean wound healing

Public title

The effect of grape seed on wound healing

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Mothers in 37-42 weeks of pregnancy - cesarean with beneath cut- 18 to 35 years of age - BMI in the range of 18/5-25 in early pregnancy - Single fetus –

Iranian -no acute or chronic illness - no-disruptive healing (disease i.e Diabetes, kidney disease, anemia, liver disease, mental) –non-consumption of drugs and tobacco - non-use of drugs affecting wound healing(Glucocorticoids, anticoagulants, immunosuppressant drugs, antibiotics and chemotherapy) - non- allergy grape seed ointment Exclusion criteria: Unwillingness to continue cooperation – irregular ointment use and as directed - Complications arising from the use of grape seed ointment - Antibiotics change from the patient's routine - Wound infection

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: **129**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences

Street address
Birjand University of Medical Sciences in Ghaffari Street

City
birjand

Postal code
971785357

Approval date
2014-11-30, 1393/09/09

Ethics committee reference number
06-09-1393

Health conditions studied

1

Description of health condition studied
cesarean

ICD-10 code
O90.0

ICD-10 code description
Disruption of caesarean section wound

Primary outcomes

1

Description
Wound Healing

Timepoint
Days of 2, 8,16 after cesarean

Method of measurement
Reeda questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
A coded package of ointment will be given to the mothers, and they will be trained on how to use it; that is,having washed their hands thouroughly and while wearing disposable gloves, they are expected to rub the ointment as much as the tip of a finger on the stitched area and repeat the steps twice a day (12 hours ± 2) from the second day after the operation to the fifteenth day .Health care points will be taught to all mothers .on the fifth and twelfth days after cesarean section,the researcher will do the follow-up by phone.Cesarean wound healing will be measured by REEDA scale. in three stages: the second day after surgery, before treatment with ointments, eighth and sixteenth days after surgery. Early intervention will be performed by the researcher and subsequent interventions by the trained mother. The first stage will be carried out at the hospital, the second stage in the clinic and the third phase by the researcher at the research center of Birjand University of Medical Sciences

Category
Treatment - Drugs

2

Description
In placebo group, placebo ointment will use instead of grape seed ointment.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-asr Hospital
Full name of responsible person
Ali Mohammad izadpanah
Street address
School of Nursing & Midwifery Ghaffari Street
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birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Ali Mohammad izadpanah
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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
Birjand University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty