

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial comparing topical effects of grape seed 5% extract ointment, placebo, and no intervention on appendectomy wound healing

Protocol summary

Study aim

To determine the impact of topical effects of grape seed 5% extract ointment on appendectomy wound healing

Design

In this randomized, controlled clinical trial study, a total of 78 patients with inclusion criteria were randomly selected and allocated into one of the three groups of control, intervention and placebo using permutation blocking.

Settings and conduct

The study will be conducted in the surgical ward of Imam Reza Hospital in Birjand in 2018. The intervention group is treated with 5% grape seed extract and the placebo group is treated by vaseline. No intervention is performed in the control group. Moreover, the study is not blinded.

Participants/Inclusion and exclusion criteria

Major inclusion criteria consist of age between 10 and 30 years; patients having undergone appendectomy; body mass index between 18.5 and 25; and McBurney's incision with maximum length of 10 centimeters. Major exclusion criteria comprise of: Appendicitis accompanied by perforation and gangrene; unwillingness to participate in the study or discontinued cooperation; sensitivity to grape seed ointment and the inability to follow-up the patient; and peritonitis.

Intervention groups

There are three groups in this study. In the intervention group, the grape seed 5% extract ointment will be applied in 1 centimeter width and one millimeter thickness onto the sutured region using sterilized, graded paper. This is performed twice a day (12 ± 2 hours) from the second to the sixteenth post-operative day. In the placebo group, vaseline ointment will be applied in 1 centimeter width and one millimeter thickness onto the sutured region using sterilized, graded paper. This is performed twice a day (12 ± 2 hours) from the second to the sixteenth post-operative day. In the control group, no ointment is used.

Main outcome variables

appendectomy wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N38**

Registration date: **2018-02-19, 1396/11/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-19, 1396/11/30**

Update count: **0**

Registration date

2018-02-19, 1396/11/30

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 3239 5680

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mbroozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Clinical trial comparing topical effects of grape seed 5% extract ointment, placebo, and no intervention on appendectomy wound healing

Public title
Effect of grape seed extract 5% ointment on appendectomy wound healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 10 and 30 years Patient having undergone appendectomy Body mass index between 18.5 and 25 McBurney's incision with maximum length of 10 centimeters

Exclusion criteria:
Appendicitis accompanied by perforation and gangrene Unwillingness to participate in the study or discontinued cooperation Sensitivity to grape seed ointment and the inability to follow-up the patient Peritonitis Suffering from immune system threatening diseases such as diabetes mellitus, uremia, cancer, malnutrition, hypertension and heart disease Use of immunosuppressive drugs

Age
From **10 years** old to **30 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be selected based on the inclusion criteria via purposive sampling method. Nonetheless, they will be assigned into study groups randomly via permutation blocking randomization. There are three cards, a, b and c, indicative of the study groups. Each participant will select one and will be allocated into the associated group.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

lr.bums.1394.359

Health conditions studied

1

Description of health condition studied

appendectomy wound healing

ICD-10 code

K38

ICD-10 code description

Other diseases of appendix

Primary outcomes

1

Description

appendectomy wound healing

Timepoint

second postoperative day (i.e., before intervention), eighth postoperative day (six days after intervention), and 16th postoperative day (14 days after intervention)

Method of measurement

REEDA (Redness, Edema, Ecchymosis, Discharge, Approximation) scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (grape seed ointment): Grape seed 5% extract ointment will be applied in 1 centimeter width and one millimeter thickness onto the sutured region using sterilized, graded paper. This is performed twice a day (12 ± 2 hours) from the second to the sixteenth post-operative day.

Category

Treatment - Other

2

Description

Control group (placebo): Vaseline ointment will be applied in 1 centimeter width and one millimeter thickness onto the sutured region using sterilized, graded paper. This is performed twice a day (12 ± 2 hours) from the second to the sixteenth post-operative day.

Category

Placebo

3

Description

Control group (No intervention): In the control group, no ointment is used.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Imam Reza Hospital

Full name of responsible person

Hosain Abbasi

Street address

Taleghani St.

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+98 56 3239 5003

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abbasi.hosain@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

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Ghaffari Ave.

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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

50

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

Birjand University of Medical Sciences

Full name of responsible person

Hosain Abbasi

Position

MSc. Student of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Hosain Abbasi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Others

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Person responsible for updating data**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

Translator

Latest degree

Master

Other areas of specialty/work

Others

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Upon the participants' request, no information can be shared.

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

Undecided - It is not yet known if there will be 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

Study Protocol

When the data will become available and for how long

In future in the paper extracted from the research project, and as long as the paper is accessible.

To whom data/document is available

all readers

Under which criteria data/document could be used

No certain criteria

From where data/document is obtainable

the extracted paper

What processes are involved for a request to access data/document

access to the journal wherein the paper is published

Comments