# 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
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**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 participants 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**

Ir.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

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Taleghani St.

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## 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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**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

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## Person responsible for updating data

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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**