Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of ostrich oil on treatment and quality of life of patients with chronic anal fissure: a randomized, double-blind clinical trial study

Protocol summary

Study aim
The effect of ostrich oil on treatment and quality of life of patients with chronic anal fissure

Design
Study is a parallel, double-blind, randomized controlled clinical trial. Each group has a sample size of 73 people and the total sample size is 146 people. Patients will be divided into two groups (group one and two) using a simple randomization method.

Settings and conduct
The study will be done in Rafsanjan city's Health Clinic. The physician, outcome evaluator, researchers and patients will be blinded. After diagnosis of the disease by the physician, the patient will be introduced to the data analysis team to be placed in one of two groups and drug will be given to the patients by this team. During the study patients will be visited by physician every 14 days and data will be collected. For assessment of relapse cases, patients also will be visited at the end of the 8th and sixteenth weeks after the end of the intervention.

Participants/Inclusion and exclusion criteria
Participants: Patients with chronic anal fissure who are 18 to 79 years. Inclusion criteria: Patients with pain and bleeding during defecation symptoms which was lasting for at least 8 weeks. exclusion criteria: Patients with other anorectal diseases, irritablebowel disease, patients who have STDs, anorectal neoplasms, anal incontinency and anal surgery, pelvic radiotherapy, patients with chronic anal fissure who are on medical treatment and patients without compliance to medical treatment.

Intervention groups
Group one (Intervention Group) will receive Glyceryl trinitrate 0.2% + Ostrich oil 50% ointment. Group two (control group) will receive 0.2% Glyceryl trinitrate ointment. Patients should apply approximately 2 cm of ointment on outer surface of the anal area every 12 hours.

Main outcome variables
Wound healing, pain, bleeding grading, quality of life, recurrence of the disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190128042525N4**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

Registration date
2020-11-02, 1399/08/12

Registrant information

Name
Gholamreza Bazmandegan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3428 0185

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-20, 1399/03/31

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of ostrich oil on treatment and quality of life of patients with chronic anal fissure: a randomized, double-blind clinical trial study

Public title
The effect of ostrich oil on treatment and quality of life of patients with chronic anal fissure: a randomized, double-blind clinical trial study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with symptoms of the disease such as pain or bleeding during defecation which was lasting for at least 8 weeks. Patients having anorectal region's posterior or anterior wound in examination in lithotomy position, which is associated with skin tag. Also horizontal smooth muscle fibers are visible at the base of the wound and sphincter is hypertrophic.

Exclusion criteria:
Patients with other anorectal diseases such as hemorrhoids, fistulas and abscesses, diabetes, tuberculosis, Crohn's and ulcerative colitis, anorectal neoplasm, leukemia and STDs such as AIDS and syphilis. Patients with history of anal surgery Patients with history of medical treatment of chronic anal fissure Patients who underwent pelvic radiotherapy Patients who are receiving chemotherapy or using immunosuppressive drugs Patients with anal incontinence Patients without medical treatment compliance

Age
From **18 years** old to **79 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **146**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups (group one and two) using random numbers' table (simple randomization method).

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind study. The drugs will be placed in the same and encoded cans, so the patient, doctor and outcome assessor will not be informed about type of prescribed drug. Coding won't be done by principal investigator and won't have access to the coding informations.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of rafsanjan University of Medical Sciences

Street address
Ali Ibn Abi-talib Square

City
Rafsanjan

Province
Kerman

Postal code
7717937555

Approval date
2020-10-04, 1399/07/13

Ethics committee reference number
IR.RUMS.REC.1399.162

Health conditions studied

1

Description of health condition studied
chronic anal fissure

ICD-10 code
K60.1

ICD-10 code description
Chronic anal fissure

Primary outcomes

1

Description
pain scoring

Timepoint
Once before starting the intervention then every 14 days after starting the intervention and twice at the end of 8th & 16th weeks after intervention.

Method of measurement
Visual Analogue Scale Questionnaire

2

Description
Wound grading

Timepoint
Once before starting the intervention then every 14 days after starting the intervention and twice at the end of 8th

& 16th weeks after intervention.

Method of measurement

By means of physical examination and grading: grade I (fresh wound with inflammation), grade II (wound with granulation tissue) and grade III (wound covered with complete epithelial tissue)

3

Description

Bleeding grading

Timepoint

Once before starting the intervention then every 14 days after starting the intervention and twice at the end of 8th & 16th weeks after intervention.

Method of measurement

By means of history taking : grade I (there is no bleeding during defecation), grade II (sometimes there is bleeding during defecation) and grade III (there is always bleeding during defecation)

Secondary outcomes

1

Description

Quality of life score

Timepoint

After complete recovery of the patient and cessation of treatment

Method of measurement

Completing the World Health Organization's (26-Question) Quality of Life Questionnaire

2

Description

Recurrence of the disease

Timepoint

At the end of 8th & 16th weeks of follow up period

Method of measurement

By history taking and physical examination

Intervention groups

1

Description

Intervention group: 100 g container contained Glyceryl trinitrate 0.2% -Ostrich oil 50% ointment will be prescribed for the patients. These drugs will be manufactured by Pasargad Rafsanjan Pharmacy. For their formulation 60 ml ostrich oil containers from Iranian cooperative Kesht Va Sanat Misagh, Kesht Ati company under the brand name Mika will be purchased. After making drugs patients will apply approximately 2 cm of it, topically on the anal area every 12 hours. The maximum treatment period will be 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: 100 g container concluded 0.2% Glyceryl trinitrate ointment will be prescribed. approximately 2 cm of it will be applied topically on the anal area every 12 hours. The maximum treatment period will be 12 weeks. The container ingredients will be produced by Pasargad Pharmacy in Rafsanjan.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rafsanjan Health clinic

Full name of responsible person
Masoumeh Taghizadeh

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Rafsanjan Health clinic, Persian Gulf Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research and Technology, Rafsanjan University of Medical Sciences

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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
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Masoumeh Taghizadeh
Position
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Latest degree
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available