Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of a topical formulation of Myrtus communis L. for patients with chronic anal fissure

Protocol summary

Study aim
Efficacy of a topical formulation of Myrtus communis L. for patients with chronic anal Fissure

Design
Double blind, randomised, parallel groups, controlled clinical trial. The number of patients is 60.

Settings and conduct
The Patients that are diagnosed as chronic anal Fissure and have condition of entrance to the study will be assigned accidentally to one of the arm studies.The topical formulation of Myrtus communis L. or diltiazem are prescribed 3 times a day in 1.5 cm for the anal region after washing by warm water.At most 2 gr Acetaminophen is prescribed to relieve the pain during the first week of study. Also, it is recommended to observe proper nutrition habits.Then the change in the evaluated index is registered by calling every week and in presence every two weeks. The time of study is 4 weeks and the place is Hamze surgical Clinic.

Participants/Inclusion and exclusion criteria
The main inclusion criteria: age 18 to 70 years; The existence of Fissure over 6 weeks; The existence of anal Fissure in physical exam; sign the consent for consciously. The main exclusion criteria: The sensitivities and allergy to the Myrtus communis L. ,Diltiazem and Acetaminophen; anal or rectal surgeries during past 3 months; The inflammatory bowel disease; Immunodeficiency diseases; The history of the ilness that needs to use pain-killing drugs continuously; cardiovascular or cerebrovascular diseases; use calcium channel blockers Background of pelvis radiotherapy; Background of main renal, liver, neurologic, hematologic and psychiatry diseases; Background of fecal incontinency; Background of chronic constipation ;pregnancy and breast feeding ;addiction to alcohol and drugs.

Intervention groups
Topical formulation of Myrtus communis L. ;on anus
Diltiazem ;three times a day, on anus

Main outcome variables
Discomfort during defication; anal pain after defication ;anal bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121031011341N10**
Registration date: **2018-04-16, 1397/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-16, 1397/01/27**
Update count: **0**

Registration date
2018-04-16, 1397/01/27

Registrant information

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Mohammad Hashem Hashempur

Name of organization / entity
Fasa University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2018-07-06, 1397/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of a topical formulation of Myrtus communis L. for patients with chronic anal fissure

Public title
Efficacy of a topical formulation of Myrtus communis L. on chronic anal fissure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria:the age over 18 years to maximum 70 years;The presence of symptoms of chronic anal fissure (including: bleeding, pain, or both,) for more than 6 weeks;the presence of anal fissure in physical exam;the appearance of horizontal fibers of internal anal sphincter and or sentinel anal tag or hypertrophic papilla;;written informed consent for inclusion.
Exclusion criteria:
Exclusion criteria:sensitivity and allergy to Myrtus communis L. or Diltiazem or Acetaminophen ;anal or rectal surgeries during 12 weeks ago;inflammatory bowel disease;others anal disease including abscess,fistula,moderate or severe eczema around anus or mass(pile);Immunodeficiency diseases;A history of diseases that require continued consumption of analgesics;any cardio-vascular or cerebro-vascular disease;consumption of calcium channel blochers drugs in general or current use of them in threatment of fissure;history of radiotherapy to pelvic region;anal fibrosis or fixed stenosis;history of important renal ,liver,neurologic,hematologic and psychiatry diseases;history of stool incontinency;history of chronic constipation or constipation during 4 weeks ago(2 episodes defication or less weekly with straining or dense stool passing);pregnancy and lactation;alcohol and opium addiction;inability to cooperate in completing forms(mood disorders or language problems)
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization : block Unit of randomization: individual Tools used in randomization: table of random numbers, sealed envlops, computer softwares How the random sequence was built : The group secretary, based on the number of envelopes (containing letters A and B, respectively, denotes the intervention and control group), identifies the patients for the use of the treatment.Thus, Allocation Concealment is fully observed and the treatment team as well as the statistical analyst are unaware of the allocation of treatment to patients and this process is unpredictable.
Blinding (investigator's opinion)
Double blinded
Blinding description
The treatment team, as well as the statistical analyst, are unaware of the allocation of treatment to patients and this process is unpredictable. After the completion of work and statistical analysis of the data are decoded
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Comimtte of Fasa University of Medical Sciences
Street address
Vice Chancellor of Research and Technolog, Fasa University of Medical Sciences, Ebn Sina square, Fasa
City
Fasa
Province
Fars
Postal code
7461686668
Approval date
2016-12-27, 1395/10/07
Ethics committee reference number
IR.FUMS.REC.1395.116

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
Discomfort during defication
Timepoint
At the beginning of intervention and every week by phone call
Method of measurement
Visual Analogue Scale

2

Description
Anal pain after defication
Timepoint
At the beginning of intervention and every week by phone call
Method of measurement
Visual Analogue Scale

3

Description
Anal bleeding
Timepoint
At the beginning of intervention and every week by phone call
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Patient's Global Impression of Improvement (PGI-I)
Timepoint
At the beginning of intervention and every two weeks in person
Method of measurement
Visual Analogue Scale

2

Description
Reepithelialization
Timepoint
At the beginning of intervention and every two weeks in person
Method of measurement
Physical exam

3

Description
Comparison of possible complications of topical formulation of Myrtus communis L.with Diltiazem
Timepoint
Every week by phone call
Method of measurement
Question by check list

4

Description
Comparison of topical formulation of Myrtus communis L.with Diltiazem at amount of acetaminophen consumption.
Timepoint
Every week by phone call
Method of measurement
Based on counting pills

Intervention groups

1

Description
Topical formulation of Myrtus communis L, three times a day on anus
Category
Treatment - Drugs

2

Description
Diltiazem, three times a day on anus
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamzeh Clinic
Full name of responsible person
Dr.Marjan mahmoodi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Fasa 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available