Comparing the effects of Terminalia Chebula Retz capsule (A product derived from Iranian traditional medicine) with placebo on the level of bleeding, pain and shrinking of the hemorrhoid pile mass: a randomized double-blind placebo-controlled trial

Protocol summary

Summary
The study purpose is assessment of the effects of terminalia chebula on hemorrhoid treatment in the patients with hemorrhoids referred to the Modarres hospital. This study is a randomized (based on randomized numbers table) double-blind placebo-controlled trial. Sample size is 40 patients in each group. Study duration is 4 weeks. In this study after taking a complete history, examination and rectosigmoidoscopy, the experimental group will receive one terminalia chebula capsule and the control group will receive one placebo capsule every 6 hours, on an empty stomach for four weeks. If the patients don’t get any response from the treatment (capsules), they can use 30 to 60 cc lactulose syrup to improve constipation and one antihemorrhoids suppository to decrease pain in each day. Inclusion criteria include 18 to 65 year-old women and men who have grade I and II hemorrhoids. Exclusion criteria include every severe disease; presence of cancer in every part of the body; every disease in anorectal except hemorrhoids; pregnant and lactating women; patients with history of using anticoagulant, antiplatelet drugs, steroids drugs, drugs with flavonoids (less than a month ago) and pain killers (less than a week ago). Primary outcomes: pain, hemorrhoids bleeding and constipation are measured respectively based on VAS, number of days and ROM III criteria before and after the intervention, at the end of every week, for four weeks. Size of mass, as primary outcome in hemorrhoids, is measured before the intervention and at the end of the intervention by rectosigmoidoscopy. Secondary outcomes: headache, vertigo, diarrhea, constipation and dry skin are measured based on questionnaire before and after the intervention, at the end of every week, for four weeks.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT2016101830372N1
Registration date: 2017-04-15, 1396/01/26
Registration timing: prospective

Last update: 
Update count: 0
Registration date
2017-04-15, 1396/01/26

Registrant information
Name
Pouran Andarkhor
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Shahid Beheshti University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date
2017-04-21, 1396/02/01
Expected recruitment end date
2020-04-20, 1399/02/01
Actual recruitment start date
empty
Actual recruitment end date
Comparing the effects of Terminalia Chebula Retz capsule (A product derived from Iranian traditional medicine) with placebo on the level of bleeding, pain and shrinking of the hemorrhoid pile mass: a randomized double-blind placebo-controlled trial

Public title
Effects of Terminalia Chebula on hemorrhoids

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria include 18 to 65 year-old women and men who have grade I and II hemorrhoids. Exclusion criteria include every severe disease; presence of cancer in every part of the body; every disease in anorectal except hemorrhoids; pregnant and lactating women; patients with history of using anticoagulant, antiplatelet drugs, steroids drugs, drugs with flavonoids (less than a month ago) and pain killers (less than a week ago).

Age
From 78 years old to 31 years old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization of this study is based on random numbers table.

Secondary Ids
empty

Ethics committees
1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
The Office of Management Research, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Evin, Shahid Chamran Highway
City
Tehran
Postal code
1985717443

Approval date
2016-10-02, 1395/07/11

Ethics committee reference number
IR.SBMU.RETECH.REC.1395.424

Health conditions studied
1

Description of health condition studied
hemorrhoids

ICD-10 code
184.2

ICD-10 code description
internal hemorrhoids without complications

Primary outcomes
1

Description
bleeding of hemorrhoids

Timepoint
Before and after the intervention, at the end of every week, for four weeks

Method of measurement
The number of days (questionnaire)

2

Description
Pain

Timepoint
Before and after the intervention, at the end of every week, for four weeks

Method of measurement
Visual Analog Scale (VAS) (questionnaire)

3

Description
The size of pilel mass

Timepoint
Before the intervention, and at the end of the intervention

Method of measurement
Rectosigmoidoscopy

4

Description
Constipation

Timepoint
Before and after the intervention, at the end of every week, for four weeks

Method of measurement
**ROM III criteria (questionnaire)**

### 5
**Description**  
Exercise

**Timepoint**  
Before and after the intervention, at the end of every week, for four weeks

**Method of measurement**  
At least half an hour daily for 4 days a week (questionnaire)

### Secondary outcomes

#### 1
**Description**  
Headache

**Timepoint**  
Before and after the intervention, at the end of every week, for four weeks

**Method of measurement**  
Visual Analog Scale (VAS) (questionnaire)

#### 2
**Description**  
Vertigo

**Timepoint**  
Before and after the intervention, at the end of every week, for four weeks

**Method of measurement**  
Grading of vertigo severity (questionnaire)

#### 3
**Description**  
Diarrhea

**Timepoint**  
Before and after the intervention, at the end of every week, for four weeks

**Method of measurement**  
Mild: <3 loose stools per day, Moderate: 3 to 10 per day, Severe: >10 per day (questionnaire)

#### 4
**Description**  
dry skin

**Timepoint**  
Before and after the intervention, at the end of every week, for four weeks

**Method of measurement**  
skin dry grading scale (questionnaire)

#### 5
**Description**  
constipation

**Timepoint**  
Before and after the intervention, at the end of every week, for four weeks

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### Intervention groups

#### 1
**Description**  
Intervention group: The intervention group receive one terminalia chebula capsule with empty stomach every 6 hours for four weeks. If the patients did not get any positive response from the capsules, they can use 30 to 60 cc lactulose syrup because constipation is disappeared and one antihemorrhoids suppository daily because pain is disappeared.

**Category**  
Treatment - Drugs

#### 2
**Description**  
Control group: The control group receive one placebo capsule with empty stomach every 6 hours for four weeks. If the patients did not get any positive response from the capsules, they can use 30 to 60 cc lactulose syrup because constipation is disappeared and one antihemorrhoids suppository daily because pain is disappeared.

**Category**  
Treatment - Drugs

### Recruitment centers

#### 1
**Recruitment center**  
Name of recruitment center  
Modarres Hospital

**Full name of responsible person**  
Pouran Andarkhor

**Street address**  
Modarres Hospital, Saadat Abad Boulevard and Yadegar Highway intersection, The end of Saadat Abad Boulevard

**City**  
Tehran

### Sponsors / Funding sources

#### 1
**Sponsor**  
Name of organization / entity  
Vice chancellor for research, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Dr. Mahmood Mosadegh

**Street address**  
Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Evin, Shahid Chamran Highway

**City**  
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
   Yes
Title of funding source
   Vice chancellor for research, Shahid Beheshti 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