

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

A randomized double blind clinical trial evaluating the effect of Colchicine & Probiotics mixture on Colon Transit Time in patient with idiopathic constipation

Protocol summary

Summary

* Goals: - A randomized double blind clinical trial evaluating the effect of Colchicine & Probiotics mixture on Colon Transit Time in patient with idiopathic constipation - Evaluating the effect of Colchicine on Colon Transit Time in patient with idiopathic constipation - Evaluating the effect of Probiotics mixture on Colon Transit Time in patient with idiopathic constipation * Design and method: 1-All patients who come to the Internal medicine clinic with complaints of constipation and have ROME III 2-Calculation of primary colonic transit time before getting the drug (5 capsules containing ten markers to calculate the transit time will be given to the patient, that eat within 24 hours and after 5 days Abdominal radiography of patients will be taken). 3- Colonoscopy patients with colonic transit time in the left or right colon, and exclusion the patients who normal colonic transit time or in the recto sigmoid part 4- Exclusion the patients who have secondary causes of constipation(Such as internal and external hemorrhoids, fissure, IBD, obstruction, polyps and tumors). 5- Divided 50 patients randomized to colchicine group and 50 patients in the prebiotic group 6- Calculation of Secondary colonic transit time after getting the drug (5 capsules containing ten markers to calculate the transit time will be given to the patient, that eat within 24 hours and after 5 days Abdominal radiography of patients will be taken). * Participants include the Inclusion criteria and exclusion of participants: Inclusion criteria: all patients who refer to the internal medicine clinic with complaints of constipation and have ROME III criteria. Exclusion criteria: uncooperative patients to enter the study and evaluation of colonic transient time; patients who normal colonic transit time or in the recto sigmoid part; patients who have secondary causes of constipation; patients who don't complete treatment. * Interventions: - The first group get 0.6 mg of colchicine per day for 4 weeks - The

second group takes a 500mg probiotic capsule per day for 4 weeks. * The main outcome variable: Colon Transit Time

General information

Acronym

The effect of two drugs on Colon Transit Time

IRCT registration information

IRCT registration number: **IRCT2014102119616N1**

Registration date: **2014-11-26, 1393/09/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-26, 1393/09/05

Registrant information

Name

Milad Rashidbeygi

Name of organization / entity

Student Research Committee, Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 1333 2142

Email address

miladrashidbeygi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-04-21, 1394/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

A randomized double blind clinical trial evaluating the effect of Colchicine & Probiotics mixture on Colon Transient Time in patient with idiopathic constipation

Public title

Evaluating the effect of Colchicine & Probiotics mixture on Colon Transient Time

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients who refer to the internal medicine clinic with complaints of constipation and have ROME III criteria. Exclusion criteria: uncooperative patients to enter the study and evaluation of colonic transient time; patients who normal colonic transit time or in the recto sigmoid part; patients who have secondary causes of constipation; patients who don't complete treatment.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ilam University of Medical Sciences

Street address

Banajo street

City

Ilam

Postal code

6939177143

Approval date

2014-03-21, 1393/01/01

Ethics committee reference number

EC/93/H/240

Health conditions studied

1

Description of health condition studied

Idiopathic Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Colon transit time

Timepoint

Before and after treatment

Method of measurement

5 capsules containing ten markers

Secondary outcomes

empty

Intervention groups

1

Description

The first group get 0.6 mg of colchicine per day for 4 weeks

Category

Treatment - Drugs

2

Description

The second group takes a 500mg probiotic capsule per day for 4 weeks. Each capsule is composed of the following materials: 1- Lactobacillus casei 7 x 10⁹ CFU/g; 2- Lactobacillus acidophilus 2 x10⁹ CFU/g; 3- Lactobacillus rhamnosus 1.5 x10⁹ CFU/g; 4- Lactobacillus bulgaricus 2 x 10⁹CFU/g; 5-Bifidobacterium breve 2 x 10⁹CFU/g; 6- Bifidobacterium longum 7 x 10⁹CFU/g; 7- Streptococcus thermophilus 1.5 x 10⁹ CFU/g.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic of Gastroenterology

Full name of responsible person

Mohammad Moradi

Street address

Sadie Street, Dr. Ghasemi Private Clinic of Gastroenterology

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Dr. Morovat Taheri Kalani

Street address

Banjo Street

City

Ilam

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ilam 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

Contact

Name of organization / entity

Student Committee Research, Ilam University of Medical Sciences

Full name of responsible person

Milad Rashidbeygi

Position

Medical Student

Other areas of specialty/work**Street address**

Banajo Street

City

Ilam

Postal code

6931985481

Phone

+98 84 1223 5700

Fax**Email**

miladrashidbeygi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Medical School, Ilam University of Medical Sciences

Full name of responsible person

Smaeil Ghasemi

Position

Pulmonary Specialty

Other areas of specialty/work**Street address**

Banjo Street

City

Ilam

Postal code**Phone**

+98 84 1223 5700

Fax**Email**

smaeilghasemi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Student Research Committee, Ilam University of Medical Sciences

Full name of responsible person

Milad Rashidbeygi

Position

Medical Student

Other areas of specialty/work**Street address**

Banajo Street

City

Ilam

Postal code

6931985481

Phone

+98 84 1223 5700

Fax**Email**

miladrashidbeygi@yahoo.com

Web page address

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