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 Transient 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 Transient Time in patient with idiopathic constipation - Evaluating the effect of Colchicine on Colon Transient Time in patient with idiopathic constipation - Evaluating the effect of Probiotics mixture on Colon Transient 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 Transient 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)

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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
Idiopatic 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
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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
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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