Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Efficacy of Herbal Medicine" Lax-asab" in treating constipation: a Randomised Control Trial

Protocol summary

Summary

We want to show the efficacy of experimental drug in Treating Constipation (based on times of defecation in each weeks and difficulties in defection) and side effects of it in comparison with placebo and resistance to it during the research. Inclusion criteria: suffering from constipation based on rom III criteria. exclusion criteria: pregnancy, GI bleeding, liver & kidney & cardiac diseases.40 cases will be selected among the patient that suffering from constipation with randomization and divided to two groups A&B(placebo, lax-asab).during 4 weeks the severity of constipation will be detected in 14 times(times in each days).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105046388N1**
Registration date: **2011-06-03, 1390/03/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-03, 1390/03/13

Registrant information

Name

Mohamadhossein Somi

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 7499

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somimh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vive chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-02-19, 1390/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Herbal Medicine" Lax-asab" in treating constipation: a Randomised Control Trial

Public title

Efficacy of " Lax-asab" in Treating Constipation

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:suffering from constipation based on romIII criteria and non-use constiepation drugs in last month.(in selection of patients we try that cases similar in age and severity of disease) exclusion criteria:secondary constipation beceause of drugs or other disease,quit the research,treatment with other antie constipation drugs,side effect of experiemental treatment.cases with hepatic,renal,cardiac,pulmonary,haematologicand brain disorder.cases with cancer,inflammatory bowel disease,hiestory of allergy to the herbals,alcholism,acetive addiction,pregnancy,breast feeding and history of gastrointestinal blleding.

Age

No age limit

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
tabriz/Tabriz University of Medical Sciences
City
tabriz
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
904

Health conditions studied

1

Description of health condition studied
constipation
ICD-10 code
K55-K63
ICD-10 code description
Constipation

Primary outcomes

1

Description
severity of constipation(based on number of defecation per week and defection difficulties)
Timepoint
befor intervention,every other day after intervention and 2 weeks after the end of intervention
Method of measurement
romIII criteria

Secondary outcomes

1

Description
probable side effect and toleration to the drug during the study
Timepoint
probable side effect and toleration to the drug during the study
Method of measurement
probable side effect and toleration to the drug during the study

Intervention groups

1

Description
dose of consumption:a glass of boiled water(0.25 liter)+a spoon of laxative herbal powder (1 gram)every other day before breakfast. research will done in 4 weeks(1 month)and in 14 times(times in each days).
Category
Treatment - Drugs

2

Description
dose of consumption:a glass of boiled water(0.25 liter)+a spoon of Prepared placebo powder(1 gram)every other day before breakfast. research will done in 4 weeks(1 month)and in 14 times(times in each days).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
emam reza hospital of tabriz/subspecial clinic of sheikh-o-raeis of tabriz(doctor somi)
Full name of responsible person
doctor somi,digestional specialty,proffesor of university
Street address
tabriz/emam reza hospital of tabriz/Subspecialty clinic of sheikh-o-raeis of tabriz(doctor somi)
City
tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person
Dr. piruzpanah

Street address
Iran,Tabriz,Tabriz University of Medical Sciences,nutritional faculty

City
Tabriz

Grant name
904

Grant code / Reference number
904

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
vice chancellor for Research of Tabriz 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
Inteligence room of Tabriz University of Medical Sciences/research room of Tabriz University of Medi

Full name of responsible person
Masood Bagheri

Position
Medical science student

Other areas of specialty/work

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Contact

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Full name of responsible person
Masood Bagheri

Position
Medical science student

Other areas of specialty/work

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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