

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of herbal mixture capsule on constipation and sexual function of postmenopausal women with chronic constipation

#### Protocol summary

##### Summary

**Objectives:** To determine the effect of herbal mixture capsule on constipation and sexual function in postmenopausal women with chronic constipation.

**Design:** Two-armed randomized controlled trial. **Conduct:** This study will be conducted on 64 postmenopausal women ages 60-40 years old referring to community health centers in Tabriz. After obtaining written informed consent, eligible individuals will complete questionnaires of constipation, demographic characteristics, Female Sexual Function and Patient Assessment of Constipation Symptoms. Then, they will be randomly assigned to two groups of intervention and control using block randomization with block sizes of 4 and 6 and the allocation ratio of 1: 1. A person not involved in the sampling will generate allocation sequence. **Participants:** Postmenopausal women ages 60-40 years old with chronic constipation according to the Rome 3 criteria. **Intervention:** The intervention group will receive herbal mixture capsules (including Cloves, Anise, Fennel, Green Raisins, Manna, Violet, Yellow Hill, Senate and Gland) and the control group will receive placebo capsules. Both groups will take drug or placebo twice a day (before lunch and before dinner) every time two capsules for four weeks. The main outcome variables include constipation and sexual activity that will be assessed by constipation questionnaire (weekly) and Female Sexual Function Index (before and 4 weeks after intervention), respectively. The secondary outcome variables include patient assessment of constipation symptom that will be assessed before, 2 and 4 weeks after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016043010324N32**

Registration date: **2016-08-14, 1395/05/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-08-14, 1395/05/24

##### Registrant information

###### Name

Mojgan Mirghafourvand

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1479 6969

###### Email address

mirghafourvandm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-08-10, 1395/05/20

##### Expected recruitment end date

2017-01-09, 1395/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of herbal mixture capsule on constipation and sexual function of postmenopausal women with chronic constipation

##### Public title

The effect of herbal mixture capsule on constipation and sexual function of postmenopausal women with chronic

constipation

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Postmenopausal women with chronic constipation according to the Rome 3 criteria; Ages between 40 and 60 years old; No allergy to herbal ingredients used in the study; Married women that are living with their partners; Having literacy for reading and writing; Having telephone number; Having willingness to participate in the study Exclusion criteria: Suffering from metabolic disease causing constipation (hypothyroidism, hyperparathyroidism and diabetes); Suffering from neuromuscular disease (multiple sclerosis, stroke, Parkinson); Suffering from diarrhea; use of medications such as opioids, antidepressants, calcium channel blockers, ibuprofen, anticonvulsants, diuretics and iron and calcium supplements; Suffering from digestive system diseases including colorectal cancer, inflammation and narrowing of the digestive system; Use of medications to relieve constipation for a week prior to the study, Hormone therapy

## Age

From **40 years** old to **60 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

##### City

Tabriz

## Postal code

## Approval date

2016-07-11, 1395/04/21

## Ethics committee reference number

IR.TBZMED.REC.1395.281

## Health conditions studied

### 1

#### Description of health condition studied

Constipation

#### ICD-10 code

K59.0

#### ICD-10 code description

Constipation

### 2

#### Description of health condition studied

Sexual dysfunction

#### ICD-10 code

F52

#### ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

## Primary outcomes

### 1

#### Description

Chronic constipation

#### Timepoint

Every week

#### Method of measurement

Questionnaire based on Rome 3 criteria including sequence of bowel movements, stool consistency, straining during defecation, feeling of incomplete evacuation during defecation, feeling of blockage disposal and the need to manipulate to facilitate defecation.

### 2

#### Description

Female sexual function

#### Timepoint

Before and four weeks after the intervention

#### Method of measurement

Female Sexual Function Index

## Secondary outcomes

### 1

#### Description

Constipation symptom

#### Timepoint

At the end of the second and fourth week after intervention

## Method of measurement

Patient Assessment of Constipation Symptom Questionnaire

## Intervention groups

### 1

#### Description

The intervention group will receive herbal mixture capsules (including Cloves, Anise, Fennel, Green Raisins, Manna, Violet, Yellow Hill, Senate and Gland) twice a day (before lunch and before dinner) every time two capsules for four weeks.

#### Category

Treatment - Drugs

### 2

#### Description

The control group will receive placebo capsules containing wheat flour for two times a day (before lunch and before dinner) and each time two capsules.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Community health centers of Tabriz city

##### Full name of responsible person

Paria Eliasvandi

##### Street address

Community health centers, Tabriz, East Azerbaijan

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammadreza Rashidi

##### Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

##### City

Tabriz

#### 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, 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

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

#### Full name of responsible person

Paria Eliasvandi

#### Position

Msc Student of Midwifery

#### Other areas of specialty/work

#### Street address

Faculty of Nursing & Midwifery, South Shariati street

#### City

Tabriz

#### Postal code

5451796499

#### Phone

+98 83 4512 4286

#### Fax

#### Email

eliasvandi.p@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

#### Full name of responsible person

Mojgan Mirghafourvand

#### Position

Assistante Professor, PhD of Reproductive Health

#### Other areas of specialty/work

#### Street address

Faculty of Nursing & Midwifery, South Shariati street

#### City

Tabriz

#### Postal code

5138947977

#### Phone

+98 41 3479 6770

#### Fax

#### Email

Mirghafourvandm@tbzmed.ac.ir,

mirg1385@yahoo.com

**Web page address**

<http://nursing.tbzmed.ac.ir>

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Faculty of Nursing & Midwifery, Tabriz University of  
Medical Sciences

**Full name of responsible person**

Paria Eliasvandi

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Msc Student of Midwifery

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Faculty of Nursing & Midwifery, South Shariati street

**City**

Tabriz

**Postal code**

5451796499

**Phone**

00

**Fax**

**Email**

[eliasvandi.p@gmail.com](mailto:eliasvandi.p@gmail.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*