

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of Liquorice and Zataria multiflora effects on gastrointestinal symptoms in ICU and CCU nurses

#### Protocol summary

##### Summary

Background and goal: According to prevalence of gastrointestinal disorders among intensive care unit (ICU) nurses, current study focuses on a comparison between effects of Glycyrrhiza glabra and Zataria multiflora on gastrointestinal disorders to introduce an efficient, safe, and affordable method to treat these disorders. Inclusion criteria: At least 1 year record of service in intensive care unit, and affected by gastrointestinal disturbances during the last week. Exclusion criteria: Affected by any severe systemic diseases. Moreover, volunteers receiving any medical treatment of stress induced symptoms (such as sleeping pills, antidepressants, or anxiolytics). Methodology: To do so, 105 ICU nurses are sampled according to the aforementioned inclusion and exclusion criteria, triple-blind (nursing, researcher and analyzer) and classified to three groups, including two intervention groups and one control group, randomly. Then, treatment is carried out through Glycyrrhiza glabra and Zataria multiflora in first and second intervention groups, respectively for 4 weeks while placebo is utilized for the control group. Primary outcome measures including reflux, abdominal pain, flatulence, constipation and diarrhea. Secondary outcome measure including dry mouth, vomiting, abdominal pain result by hunger. Then, existence of gastrointestinal symptoms and their intensity in nurses (based on visual analog scale (VAS) grade) are evaluated via a questionnaire before and after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014100419330N2**

Registration date: **2014-11-22, 1393/09/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-11-22, 1393/09/01

##### Registrant information

###### Name

Zaynab Vafa Arani

###### Name of organization / entity

Arak university of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5473 8565

###### Email address

z.vafaarany@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Science

##### Expected recruitment start date

2014-10-23, 1393/08/01

##### Expected recruitment end date

2014-11-22, 1393/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Liquorice and Zataria multiflora effects on gastrointestinal symptoms in ICU and CCU nurses

##### Public title

A comparison between effects of Glycyrrhiza glabra and Zataria multiflora on gastrointestinal disorders of ICU nurses

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: To be eligible for this trial, each volunteer needs to meet the following criteria at a screening and baseline visit: Volunteers between 20 to 55 years old, male or female, capable of giving informed consent, to have at least 1 year record of service in intensive care unit, and affected by gastrointestinal disturbances during the last week. Exclusion criteria: Nonconformity with medication regimen, being affected by any severe systemic diseases. Moreover, volunteers that are receiving any medical treatment of stress induced symptoms (such as sleeping pills, antidepressants, or anxiolytics) or those who have taken such treatment since 3 months ago or later are also excluded. In addition, those volunteers who are using nicotine or who have weaned since 6 months ago are excluded.

### **Age**

From **20 years** old to **55 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **105**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Triple blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

A random number between 1 and 105 is assigned to each of nurses (satisfying inclusion criteria) and then they classified to three groups via random number generation.

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Arak University of Medical Science

##### **Street address**

Basij square, Sardasht, Arak, Iran

##### **City**

Arak

##### **Postal code**

#### **Approval date**

2014-07-22, 1393/04/31

## **Ethics committee reference number**

1915/1/5/29/پ

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Irritable bowel syndrome

#### **ICD-10 code**

k58

#### **ICD-10 code description**

Irritable bowel syndrome

### **2**

#### **Description of health condition studied**

Constipation

#### **ICD-10 code**

k59.0

#### **ICD-10 code description**

Constipation

### **3**

#### **Description of health condition studied**

Functional diarrhoea

#### **ICD-10 code**

k59.1

#### **ICD-10 code description**

Functional diarrhoea

### **4**

#### **Description of health condition studied**

Fissure and fistula of anal and rectal regions

#### **ICD-10 code**

k60

#### **ICD-10 code description**

Fissure and fistula of anal and rectal regions

### **5**

#### **Description of health condition studied**

Abscess of anal and rectal regions

#### **ICD-10 code**

k61

#### **ICD-10 code description**

Abscess of anal and rectal regions

### **6**

#### **Description of health condition studied**

Other diseases of anus and rectum

#### **ICD-10 code**

k62

#### **ICD-10 code description**

Other diseases of anus and rectum

### **7**

#### **Description of health condition studied**

Other diseases of intestine

**ICD-10 code**

k63

**ICD-10 code description**

Other diseases of intestine

**8****Description of health condition studied**

Other specified diseases of digestive system

**ICD-10 code**

k92.8

**ICD-10 code description**

Other specified diseases of digestive system

**9****Description of health condition studied**

Disease of digestive system, unspecified

**ICD-10 code**

K92.9

**ICD-10 code description**

Disease of digestive system, unspecified

**Primary outcomes****1****Description**

Abdominal pain

**Timepoint**

4 weeks

**Method of measurement**

Questionnaire

**2****Description**

Pyrosis

**Timepoint**

4 weeks

**Method of measurement**

Questionnaire

**Secondary outcomes****1****Description**

Change in bowel habits (Constipation, Diarrhea)

**Timepoint**

4 Weeks

**Method of measurement**

Questionnaire

**2****Description**

Reflux

**Timepoint**

4 Weeks

**Method of measurement**

Questionnaire

**3****Description**

Flatulence

**Timepoint**

4 Weeks

**Method of measurement**

Questionnaire

**4****Description**

Xerostomia

**Timepoint**

4 Weeks

**Method of measurement**

Questionnaire

**5****Description**

Vomiting

**Timepoint**

4 Weeks

**Method of measurement**

Questionnaire

**6****Description**

Abdominal pain caused by hunger

**Timepoint**

4 Weeks

**Method of measurement**

Questionnaire

**Intervention groups****1****Description**

First intervention group: First intervention group treatment is carried out via Glycyrrhiza glabra (3 capsule D-reglis: 650mg per day) during 4 weeks.

**Category**

Treatment - Drugs

**2****Description**

Control group: In control group, placebo is utilized (3 capsule starches per day) during 4 weeks.

**Category**

Placebo

**3****Description**

Second intervention group: Second intervention group treatment is carried out via Zataria multiflora (3 capsule gastrolit: 20 mg per day) during 4 week.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Shahid Beheshti hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Kashan

2

### Recruitment center

**Name of recruitment center**  
Imam Ali Heart Center  
**Full name of responsible person**  
**Street address**  
**City**  
Kashan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice Chancellor for Research of Arak University of  
Medical Science  
**Full name of responsible person**  
Dr. Davood Hekmatpou  
**Street address**  
Amir-al-momenin hospital, Basij square, Sardasht,  
Arak, Iran  
**City**  
Arak

### 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 of Arak University of  
Medical Science

### 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**  
Arak university of medical science

### Full name of responsible person

Dr. Sharareh Khosravi

### Position

Nursing Ph.D.

### Other areas of specialty/work

### Street address

Amir-al-momenin hospital, Basij square, Sardasht,  
Arak, Iran

### City

Arak

### Postal code

### Phone

+98 86 3417 3503

### Fax

### Email

shararehkh2011@yahoo.com

### Web page address

## Person responsible for scientific inquiries

### Contact

### Name of organization / entity

Arak university of medical science

### Full name of responsible person

Dr. Sharareh khosravi

### Position

Nursing, Ph.D.

### Other areas of specialty/work

### Street address

Amir-al-momenin hospital, Basij square, Sardasht,  
Arak, Iran

### City

Arak

### Postal code

### Phone

+98 86 3417 3503

### Fax

### Email

shararehkh2011@yahoo.com

### Web page address

## Person responsible for updating data

### Contact

### Name of organization / entity

Arak University of Medical Science

### Full name of responsible person

Zaynab Vafa Arani

### Position

B.Sc.

### Other areas of specialty/work

### Street address

No. 11, Amir Kabir St.

### City

Aran & Bidgol

### Postal code

8741646456

### Phone

+98 31 5472 3165

### Fax

### Email

zvafa62@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*