

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparing the effect of pharmacotherapy and hypnotherapy with pharmacotherapy on quality of life and symptoms of irritable bowel syndrome patients

#### Protocol summary

##### Summary

The aim of the present study is to determine the impact of hypnotherapy alongside pharmacotherapy with pharmacotherapy alone on quality of life and symptoms of irritable bowel syndrome patients. This is a clinical trial study in which 34 patients will select using Rome-III criteria. Inclusion criteria will include of diagnostic irritable bowel syndrome base on Rome-III criteria and participate of volunteere in the project and exclusion criteria will include history of receiving psychotherapy during 6 mounts ago and irritable bowel syndrome with constipation and mix predominance. ptients will randomly divided into two groups of 17 patients. The first group underwent hypnotherapy alongside pharmacotherapy. The second group receive pharmacotherapy alone. The quality of life (QOL-IBS) and Bowel Symptom Severity and Frequency (BSS-FS) will assessment for both groups befor and after therapeutic intervention. Patients will follow-up for a peiod of 6 month after the intervention.

#### General information

##### Acronym

Efficacy of hypnotherapy with pharmacotherapy and pharmacotherapy on quality of life and symptoms

##### IRCT registration information

IRCT registration number: **IRCT201210268253N2**

Registration date: **2012-12-09, 1391/09/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-12-09, 1391/09/19

##### Registrant information

##### Name

Sayed Kamal Solati

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38133338157

##### Email address

kamal\_solati@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahrekord University of Medical Sciences

##### Expected recruitment start date

2012-07-05, 1391/04/15

##### Expected recruitment end date

2012-09-05, 1391/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of pharmacotherapy and hypnotherapy with pharmacotherapy on quality of life and symptoms of irritable bowel syndrome patients

##### Public title

The effecacy hypnotherapy on treatment of irritable bowel syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The presence of diagnostic irritable bowel syndrome base on Rome-III criteria; Participate of

volunteered in the project;The minimum level of literacy in primary. Exclusion criteria: The presence of organic damage and cognitive dysfunctions such as dementia and mental retardation;The presence of history of receiving psychotherapy during 6 months ago;Irritable bowel syndrome with constipation and mix predominance.

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 34

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahrekord University of Medical Sciences

##### Street address

Shahrekord University of Medical Sciences,Kashani street,Shahrekord

##### City

Shahrekord

##### Postal code

8815713471

#### Approval date

2012-05-21, 1391/03/01

#### Ethics committee reference number

91-3-1

### 2

#### Ethics committee

##### Name of ethics committee

Shahrekord University of Medical Sciences

##### Street address

Shahrekord University of Medical Sciences,Kashani street,Shahrekord

##### City

Shahrekord

#### Postal code

8815713471

#### Approval date

2012-08-20, 1391/05/30

#### Ethics committee reference number

1-3-91

## Health conditions studied

### 1

#### Description of health condition studied

سندرم روده تحریک پذیر

#### ICD-10 code

K58

#### ICD-10 code description

Irritable bowel syndrome

## Primary outcomes

### 1

#### Description

Quality of Life

#### Timepoint

before of intervention,after of intervention and after 6 intervention (follow-up)

#### Method of measurement

Quality of life test

### 2

#### Description

Bowel symptoms of severity and frequency

#### Timepoint

before of intervention,after of intervention and after 6 intervention (follow-up)

#### Method of measurement

Bowel symptoms of severity and frequency scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Hypnotherapy with Pharmacotherapy. In this group,patients will underwent for 5 hypnotherapy session,in addition to current pharmacotherapy.

#### Category

Treatment - Other

### 2

#### Description

Control group: Pharmacotherapy. This group will underwent current pharmacotherapy alone.

#### Category

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Psychiatry ward,Hajar hospital,Parastar  
Street,Shahrekord,Iran

##### Full name of responsible person

Sayed Kamal Solati

##### Street address

Psychiatry ward,Hajar hospital,Parastar  
Street,Shahrekord,Iran

##### City

Shahrekord

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Full name of responsible person

Sayed Kamal Solati

##### Street address

Psychiatry Ward,Hajar Hospital,Parastar  
Street,Shahrekord,Iran

##### City

Shahrekord

##### Grant name

91-3-1

##### Grant code / Reference number

91-3-1

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

Yes

##### Title of funding source

Shahrekord 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

Shahrekord University of Medical Sciences

##### Full name of responsible person

Sayed Kamal Solati

##### Position

PhD in Psychology,Assistant Professor

#### Other areas of specialty/work

##### Street address

Psychiatry Ward,Hajar hospital,Parastar  
Street,Shahrekord,Iran

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

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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*