

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Aug 2026

### A comparative study of the effects of pyridostigmine and bisacodyl in Refractory constipation.

#### Protocol summary

##### Summary

Patients who suffer from chronic constipation and resistant to common treatments are chosen. Patients were between 18 - 75 years old and from both gender. in spite of the current treatments for at least six months, they do not cure. exclusion criteria were: any underlying disease affecting gastrointestinal motility, gastrointestinal motility drugs and patients who had a history of abdominal surgery. the present study is a clinical trial among 70 patients with chronic constipation randomly were divided in two groups of 35. VAS score is recorded during bowel movements or constipation and satisfaction of patients before medication is also recorded . based on random number allocation the patient were divided into two groups. group 1 is treated with Bisacodyl 5mg every 8 hour for 4 weeks and group 2 is treated with Prydostigmine 60mg every 8 hour for 4 weeks. To avoid any systematic error study is double blinded. All drugs are encapsulated and encoded by pharmacologists So that neither patients nor physicians are not aware of the type and method of administration. Periodically every two weeks after the initial treatment , VAS score, defecate score and satisfaction is obtained from all patients . Finally all the data are analyzed using appropriate statistical tests.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201405227080N2**

Registration date: **2014-12-05, 1393/09/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-12-05, 1393/09/14

#### Registrant information

##### Name

Javad Shokri Shirvani

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1223 8284

##### Email address

drshokrij@mubabol.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Research Babol University of Medical Sciences

#### Expected recruitment start date

2012-06-01, 1391/03/12

#### Expected recruitment end date

2014-08-03, 1393/05/12

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparative study of the effects of pyridostigmine and bisacodyl in Refractory constipation.

#### Public title

Treatment of chronic and resistant conventional therapy constipation .

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients who have constipation for more than a year and have not responded to conventional treatments . Exclusion criteria: age below 18 and above 75, the underlying disease affecting

gastrointestinal motility (eg, hypothyroidism, diabetes and neurological diseases), the use of drugs affecting gastrointestinal motility (eg calcium channel blockers), history of abdominal surgery

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### 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

Ethics Committee Babol University of Medical Sciences

##### Street address

University Sq, Ganje Afrooze Ave

##### City

Babol

##### Postal code

4717641367

#### Approval date

2014-04-22, 1393/02/02

#### Ethics committee reference number

4026

## Health conditions studied

### 1

#### Description of health condition studied

Constipation

#### ICD-10 code

K90,K91,K9

#### ICD-10 code description

Other diseases of the digestive system

## Primary outcomes

### 1

#### Description

The shape of stool

#### Timepoint

At the start of the intervention, Two weeks later, Four weeks later

#### Method of measurement

Based on image measurement

### 2

#### Description

The number of stools per week

#### Timepoint

At the start of the intervention, Two weeks later, Four weeks later

#### Method of measurement

Questionnaire

### 3

#### Description

Feeling of incomplete defecation

#### Timepoint

At the start of the intervention, Two weeks later, Four weeks later

#### Method of measurement

Questionnaire

### 4

#### Description

Duration of Defecation per time

#### Timepoint

At the start of the intervention, Two weeks later, Four weeks later

#### Method of measurement

Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: 4 weeks use of pyridostigmine( 60mg, Every 8 hours )

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: 4 weeks use of bisacodyl (5mg, Every 8 hours )

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ayatollah Rohani Hospital

**Full name of responsible person**

Dr Javad Shokri Shirvani

**Street address**

Interior section, Ayatollah Rohani Hospital, University  
Sq, Ganjafroz Street

**City**

Babol

### 2

#### Recruitment center

**Name of recruitment center**

Shahid Beheshti Hospital

**Full name of responsible person**

Dr Javad Shokri Shirvani

**Street address**

Interior section, shahid Beheshti Hospital , University  
Sq, Ganjafroz Street

**City**

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Babol University of  
Medical Sciences

**Full name of responsible person**

Dr. Ali Akbar Moghadamnia

**Street address**

University Sq, Ganje Afrooze Ave

**City**

Babol

**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 Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Dr Javad Shokri Shirvani

**Position**

Gastroenterologist

**Other areas of specialty/work****Street address**

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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*