

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effectiveness of premedication with Dimethicone and N-acetyl cysteine for improving visibility during upper endoscopy

#### Protocol summary

##### Summary

This study aims to determine the effect of using either Dimethicone or N- acetyl cysteine prior to upper endoscopy to remove air bubbles, mucus and improve visibility. In this placebo controlled, double blind, randomized clinical trial, a total of 140 patients referred to endoscopy centers are enrolled after obtaining informed consent and removal of patients with at least one of the following characteristics: Patients with previous history of gastrointestinal surgery, patients with gastrointestinal malignancies, patients with gastrointestinal bleeding, Pregnant patients, patients with history of gastrointestinal caustic substance (acid - base), diabetic patients, patients with asthma or history of allergies. Then patients are randomly grouped into 4 discrete groups: Group A (control): 100 cc of plain warm water 20 minutes before endoscopy; Group B: 100 mg of Dimethicone in 100 cc of warm water 20 minutes before endoscopy; Group C: 600 mg of N- acetyl cysteine in 100 cc of warm water 20 minutes before endoscopy; Group D: 100 mg of Dimethicone and 600 mg of N- acetyl cysteine in 100 cc of warm water 20 minutes before endoscopy. Then Mucosal visibility in four discrete part of stomach would be checked by a fixed endoscopist and scoring, based on a specific scoring system, would be done.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903314226N1**

Registration date: **2010-07-23, 1389/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-07-23, 1389/05/01

##### Registrant information

###### Name

Gholam Reza Sivandzadeh

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1647 4316

###### Email address

ghsivand@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice-chancellery of research affairs in Shiraz University of Medical Sciences (as a thesis)

##### Expected recruitment start date

2010-07-23, 1389/05/01

##### Expected recruitment end date

2010-09-06, 1389/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of premedication with Dimethicone and N-acetyl cysteine for improving visibility during upper endoscopy

##### Public title

Effectiveness of Dimethicone and N-acetyl cysteine in improving stomach mucosal visibility

##### Purpose

Diagnostic

##### Inclusion/Exclusion criteria

Inclusion criteria: all patients referred to endoscopy centers, Motahari clinics and Faghihi hospital in shiraz, Iran, after obtaining informed consent. Exclusion criteria: Patients with previous history of gastrointestinal surgery, patients with gastrointestinal malignancies, patients with gastrointestinal bleeding, Pregnant patients, patients with a history of digestive caustic substance (acid -base), diabetic patients, patients with asthma or allergy.

#### **Age**

From **18 years** old to **85 years** old

#### **Gender**

Both

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **140**

#### **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**

Shiraz University of Medical Sciences

##### **Street address**

Near to Namazi Square, Zand St.

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2010-06-01, 1389/03/11

#### **Ethics committee reference number**

CT-88-5072

### **Health conditions studied**

#### **1**

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

upper endoscopy

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

K20-K31

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

Diseases of oesophagus, stomach and duodenum

### **Primary outcomes**

#### **1**

#### **Description**

Amount of air bubbles and mucus present in four discrete regions of stomach

#### **Timepoint**

20 min after drug solution taking and during endoscopy

#### **Method of measurement**

lack of bubbles or amount of mucus and volumes of water needed to wash it away

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

#### **Description**

Group A (control): 100 cc of plain warm water 20 minutes before endoscopy

#### **Category**

Placebo

#### **2**

#### **Description**

Group D: 100 mg of Dimethicone and 600 mg of N-acetyl cysteine in 100 cc of warm water 20 minutes before endoscopy

#### **Category**

Diagnosis

#### **3**

#### **Description**

Group B: 100 mg of Dimethicone in 100 cc of warm water 20 minutes before endoscopy

#### **Category**

Diagnosis

#### **4**

#### **Description**

Group C: 600 mg of N-acetyl cysteine in 100 cc of warm water 20 minutes before endoscopy

#### **Category**

Diagnosis

### **Recruitment centers**

#### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Motahari Clinic Endoscopy Center

##### **Full name of responsible person**

Dr Seyed Mohammad Kazem Hosseini Asl, Associate prof.

**Street address**

Second Floor of Motahari Clinic Building, Namazi Square

**City**

Shiraz

**2****Recruitment center****Name of recruitment center**

Faghihi Hospital Endoscopy Center

**Full name of responsible person**

Dr Seyed Mohammad Kazem Hosseini Asl, Associate prof.

**Street address**

Faghihi Hospital, After Setad square, Zand Avenue

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-chancellery of research affairs in Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Hossein Dabaghmanesh

**Street address**

Seventh Floor, Central Building of Shiraz University of Medical Sciences, next to the Red Crescent, Zand Avenue

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellery of research affairs in Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Gholam Reza Sivandzadeh

**Position**

Residency in Internal medicine

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

Namazi Hospital, Bureau of Internal Medicine Ward

**City**

Shiraz

**Postal code****Phone**

+98 71 1647 4316

**Fax**

+98 71 1647 4316

**Email**

ghsivand@sums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Kazem Hosseini Asl

**Position**

Faculty member, Associate Professor, Department of Internal Medicine, Specialty of Gastroenterology

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

Namazi Hospital, Bureau of Internal Medicine Ward

**City**

Shiraz

**Postal code****Phone**

+98 71 1647 4316

**Fax**

+98 71 1647 4316

**Email**

hosseiniasl@sums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Kazem Hosseini Asl

**Position**

Faculty member, Associate Professor

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

Namazi Hospital, Bureau of Internal Medicine Ward

**City**

Shiraz

**Postal code****Phone****Fax****Email****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*