

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

2010-07-23, 1389/05/01

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

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

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

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Full name of responsible person

Seyed Mohammad Kazem Hosseini Asl

Position

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

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Full name of responsible person

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Position

Faculty member, Associate Professor

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

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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