

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Study of the effectiveness of Sclerotherapy for treatment of idiopathic achalasia cases which are resistance to or have poor candidate of pneumatic balloon dilation

#### Protocol summary

##### Summary

In this study Achalasic patients who are resistant or poor candidate for PD(pneumatic dilation),are treated by EO injection. EO is injected into the LES portion of patients" esophagous, and patients have been followed 1.5-3-6-9-12 months after the last injection. Our primary outcomes in this study will be clinical response which is assessed by symptom scoring and also timed esophagogram change after EO injection. In addition,complications ,resistance and relapse of symptoms will be followed. 10 ml of 2.5% EO was applied by diluting 5% EO 1:1 (v/v) in normal saline. 10 mL of diluted EO are injected in divided dose through a 5 mm sclerotherapy needle into each of four quadrants, approximately 3 cm above the LES.Injection will be repeated every two weeks up to six weeks.patients with sever complications such as perforation will exclude.In relapsed cases EO injection will be repeated with the previous protocol. patients have evaluated before and after the treatment(1.5-3-6-9-12 months after the last injection) by symptom scoring and timed barium esophago gram(height and volume of retain barium in 5th minute).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903234170N1**  
Registration date: **2011-01-20, 1389/10/30**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-01-20, 1389/10/30

#### Registrant information

##### Name

Ramin Niknam

##### Name of organization / entity

DDRC

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8241 5000

##### Email address

niknam@ddrc.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

TUMS (Tehran University of Medical Sciences), DDRC (digestive disease research center)

#### Expected recruitment start date

2007-06-24, 1386/04/03

#### Expected recruitment end date

2010-06-24, 1389/04/03

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Study of the effectiveness of Sclerotherapy for treatment of idiopathic achalasia cases which are resistance to or have poor candidate of pneumatic balloon dilation

#### Public title

efficacy of sclerotherapy for treatment of achalasia

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion: poor candidate of PDT(sigmoid)

esophagus, epiphrenic diverticula, patients with poor operative risk, patients with poor cooperative history for PDT or surgery), idiopathic achalasia, resistance to PDT, cooperative patients. Exclusion: patients with poor cooperation, secondary achalasia, good response to PDT or other standard therapy, pregnancy or breast feeding, active illicit drug or alcohol abuse, prior history of allergic reactions to agents belonging to the EO family, pregnancy or breast feeding; a history of severe co-morbid disease. Informed consent was obtained from each patient included in the study.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 13

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary IDs**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

DDRC (digestive disease researching center) ethics committee

**Street address**

Shariati hospital, northern Karegar Ave., Tehran

**City**

Tehran

**Postal code**

1411713135

**Approval date**

2010-03-17, 1388/12/26

**Ethics committee reference number**

FWA00001331 \_ DHHS-IRB00001641

**Health conditions studied****1****Description of health condition studied**

idiopathic achalasia

**ICD-10 code**

K22.0

**ICD-10 code description**

Achalasia of cardia

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

clinical response (clinical symptoms)

**Timepoint**

pretreatment and 1.5, 3, 6, 9 and 12 months after the last injection

**Method of measurement**

Questionnaire

**2****Description**

barium volume (cubic ml) in 5th minute

**Timepoint**

pretreatment/post treatment (1.5-6-12 months after last injection)

**Method of measurement**

timed barium esophagogram

**3****Description**

barium height (mm) in 5th minute

**Timepoint**

pretreatment/post treatment (1.5-6-12 months after last injection)

**Method of measurement**

timed barium esophagogram

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

perforation or bleeding of injection site

**Timepoint**

during injection

**Method of measurement**

endoscopy

**2****Description**

esophagitis

**Timepoint**

during injection

**Method of measurement**

endoscopy

**3****Description**

chest pain

**Timepoint**

first 24 hours after each injection

**Method of measurement**

observation and history taking

**Intervention groups**

1

**Description**

We have used 10cc of Ethanole amine oleat 2.5% divided in four parts and injected into 4 quadrants of LES (about 2 cm above Z-line) .

**Category**

Treatment - Drugs

**Recruitment centers**

1

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

DDRC (digestive disease research center)

**Full name of responsible person**

Dr. Javad Mikaeli -Dr. Ramin Niknam

**Street address**

Shariati hospital , northern Karegar Ave.,

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor****Name of organization / entity**

Research assistance of Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

**Street address**

Tehran University of Medical Sciences

**City**

Tehran

**Grant name**

ندارد

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

Yes

**Title of funding source**

Research assistance of Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Javad Mikaeli -Dr. Ramin Niknam

**Position**

professor /MD

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

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**Person responsible for scientific inquiries****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*