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,epipherenic 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 resonse (clinical symptoms)
Timepoint
pretreatment and 1.5, 3, 6, 9 and 12 months after thelast injection
Method of measurement
Questionnaire

2

Description
barium volume (cubic ml)in 5th minute
Timepoint
pretreatment/post treatment (1.5-6-12months after last injection)
Method of measurement
timed barium esophagogarm

3

Description
barium height(mm)in 5th minute
Timepoint
pretreatment/post treatment(1.5-6-12months after last injection)
Method of measurement
timed barium esophagogarm

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
Shariati hospital , northern Karegar Ave.,
City
Tehran
Postal code
1411713135
Phone
+98 21 8241 5110
Fax
+98 21 8241 5400
Email
mikaeli@ams.ac.ir; niknam@ddrc.ac.ir
Web page address
www.DDRC.ac.ir

Person responsible for scientific 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
Shariati hospital , northern Karegar Ave.,
City
Tehran
Postal code
1411713135
Phone
+98 21 8241 5110
Fax
+98 21 8241 5400
Email
mikaeli@ams.ac.ir; niknam@ddrc.ac.ir
Web page address
www.DDRC.ac.ir

Person responsible for updating data

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
Shariati hospital , northern Karegar Ave.,
City
Tehran
Postal code
1411713135
Phone
+98 21 8241 5110
Fax
+98 21 8241 5400
Email
mikaeli@ams.ac.ir; niknam@ddrc.ac.ir
Web page address
www.DDRC.ac.ir

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