Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of EUS-guided alcohol ablation effectiveness in treatment of insolinoma

Protocol summary

Summary

After localizing the site of the tumor by EUS, fine needle aspiration of the tumor will be performed for cytological evaluation. At least three passes of FNA with a 22-guage needle (COOK) will be taken. The samples will be placed into 70% ethanol and sent for cell block preparation and cytological evaluation. Then, a total of 6 ml of 95% ethanol will be injected during the same session using linear array echo-endoscope guidance. The patients will be hospitalized for 48 hours. The patients will be received dextrose 10% (1000 ml every 8 hours) during the first 24 hours after alcohol injection. Periodic visits of the patient will be performed during the hospitalization. The patients will be monitored for any symptoms (e.g. abdominal pain, nausea, vomiting, etc.). Serum levels of amylase and lipase will be checked at hour 12, hour 24 and hour 48 post-procedure. Outcome measures: •Fasting plasma glucose level at day 0 (before the procedure), day 1, month 1, month 3, month 6, month 12 post-procedure •EUS of the pancreas to evaluate tumor remission at month 3, and month 12 post-procedure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201098635N2**
Registration date: **2012-05-09, 1391/02/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-05-09, 1391/02/20

Registrant information

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Mehdi Mohammadnejad
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of EUS-guided alcohol ablation effectiveness in treatment of insolinoma

Public title

Evaluation of EUS-guided alcohol ablation effectiveness in treatment of insolinoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: •Biochemically proven solitary insulinoma •Ages between 18 and 80 years old Exclusion criteria: •Insulinoma size of 2 cm or more •Presence of lymph node, or vascular involvement of the tumor in EUS or spiral CT scan •Presence of liver or other distant metastases in the spiral CT scan •Presence of MEN-1 syndrome •Presence of multiple insulinomas •Inability to

localize the tumor by EUS •Unwilling to assign inform consent

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Not randomized

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
Tehran university of medical sciences

Street address
Tehran university of medical sciences, Ghods ave, Keshavarz boulvard, Tehran

City
Tehran

Postal code

Approval date
2012-05-02, 1391/02/13

Ethics committee reference number
16322

Health conditions studied

1

Description of health condition studied
insulinoma

ICD-10 code
C25.9

ICD-10 code description
Pancreas, unspecified

Primary outcomes

1

Description
The effectivenrss of the process

Timepoint
In the first and third month after treatment, BS level, and also in the third month the size of tumor would be measured and regiter by (EUS) method.

Method of measurement
According to check list

2

Description
Serum amylase

Timepoint
12, 24 and48 hours post(EUS)

Method of measurement
Patients blood sampling

3

Description
Serum lipase

Timepoint
12, 24 and 48 hours post(EUS)

Method of measurement
Patient's blood sampling

4

Description
The procedure's time

Timepoint
During sonography and alcohol injection

Method of measurement
According to endoscopist's report

Secondary outcomes

1

Description
Complications

Timepoint
During first 48 hours of admission

Method of measurement
According to physical exams and tests

2

Description
Admission time

Timepoint
The average of the patient's spending days while the procedure untill discharging from the hospital

Method of measurement
According to the file

Intervention groups

1

Description

After localizing the site of the tumor by EUS, fine needle aspiration of the tumor will be performed for cytological evaluation. At least three passes of FNA with a 22-guage needle (COOK) will be taken. The samples will be placed into 70% ethanol and sent for cell block preparation and cytological evaluation. Then, a total of 6 ml of 95% ethanol will be injected during the same session using linear array echo-endoscope guidance. The patients will be hospitalized for 48 hours. The patients will be received dextrose 10% (1000 ml every 8 hours) during the first 24 hours after alcohol injection. Periodic visits of the patient will be performed during the hospitalization. The patients will be monitored for any symptoms (e.g. abdominal pain, nausea, vomiting, etc.). Serum levels of amylase and lipase will be checked at hour 12, hour 24 and hour 48 post-procedure. Outcome measures: •Fasting plasma glucose level at day 0 (before the procedure), day 1, month 1, month 3, month 6, month 12 post-procedure •EUS of the pancreas to evaluate tumor remission at month 3, and month 12 post-procedure

Category

Treatment - Drugs

2

Description

Control group: the patients with insulinoma treating by surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tehran University of Medical Sciences

Full name of responsible person

Ms. Malmir

Street address

class 5, Tehran University of Medical Sciences, Ghods ave, Keshavarz boulvard, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy 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

Firoozgar hospital

Full name of responsible person

Neda rabiei

Position

General physician

Other areas of specialty/work

Street address

Resaerch center of Gastroentrology and liver diseases, Firoozgar hospital, Beh afarin st, Vali asr sq.

City

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Fax

Email

Neda.rabiei@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shariati hospital

Full name of responsible person

Mehdi Mohammadnejad

Position

Specialist in gastroentrology and liver diseases

Other areas of specialty/work

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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