

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Pain relieving effect of intra-operative chemical splanchnicectomy of celiac ganglions in patients with resectable pancreatic or gastric masses: a randomized clinical trial

Protocol summary

Summary

The aim of this study is to evaluate the effect of intra-operative chemical splanchnicectomy on pain intensity during first fourth month after surgical resection of gastric and pancreatic masses. Approved diagnosis of resectable pancreatic or gastric neoplasms is the main inclusion criteria. Unresectable masses or history of neo-adjuvant chemotherapy are considered as main exclusion criteria. Sample size is calculated by use of Nomogram and comparison of two means equation. Eighty eight patients will be involved in this study, including 44 cases of gastric cancer and 44 cases of pancreatic cancer, each group will be divided into two subgroups by simple randomization after taking informed consent. For the case subgroups, 20 cc of 99.99% ethanol (of German Merk Company) which is diluted to 50% solution with normal saline will be injected to each of celiac ganglions at both sides of supra-pancreatic aorta. The control subgroups do not received any injection. This study is designed as a double-blinded clinical trial so neither reasearchers nor patients are not aware of injected solution. Before surgery, one, two and four days after surgery, discharge time, one month, two months and four months after surgery, researcher will ask patients to evaluate their pain intensity by the aid of Visual Analogue Scale (VAS) for pain. The result will be analyzed with latest version of SPSS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022821269N1**
Registration date: **2015-10-30, 1394/08/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-30, 1394/08/08

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

This article has registered as a thesis and is financially supported by Gastrointestinal Research Center of Firoozgar General Hospital.

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pain relieving effect of intra-operative chemical splanchnicectomy of celiac ganglions in patients with resectable pancreatic or gastric masses: a randomized clinical trial

Public title

Effect of intraoperative Ethanol injection to nerve ganglions on pain intensity after surgical resection of gastric and pancreatic masses

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Resectable pancreatic cancer or gastric cancer; Obtaining informed consent for probable alcohol injection during surgery. Exclusion criteria: Unresectable pancreatic cancer; Unresectable gastric cancer; Patients those who underwent neo-adjuvant chemotherapy; Patients who dissatisfaction with the procedures; Patients who expires before 4 month after operation; Prolonged post-operation hospitalization (more than 15 days) due to surgical complications; Age less than 15 or more than 80 year; History of prolonged consumption of opioids, NSAIDS, analgesic and anti-depressant drugs; Cardiac or pulmonary diseases; Sensitivity to opioid drugs; Psychological disorders; Abnormal arterial blood gas analysis; Happening of surgical complications or any other signs that results in disability to complete pain scale questionnaire (such as loss of consciousness).

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

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**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway.

City

Tehran

Postal code

1449614535

Approval date

2015-04-14, 1394/01/25

Ethics committee reference number

IR.IUMS.REC.1394 24479

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

Pain intensity after gastric or pancreatic neoplasm resection

ICD-10 code

R10.1

ICD-10 code description

Pain localized to upper abdomen

2**Description of health condition studied**

Resectable malignant neoplasm of head of pancreas

ICD-10 code

C25.0

ICD-10 code description

Malignant neoplasm of head of pancreas

3**Description of health condition studied**

Resectable malignant neoplasm of stomach

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

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

Severity of abdominal pain

Timepoint

Before surgery, one, two and four days after surgery, discharge time, one, two and four months after surgery

Method of measurement

Visual Analogue Scale (VAS) questionnaire

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

Hospitalization time

Timepoint

Discharge time

Method of measurement

Number of days that patient stays at hospital after surgery

2

Description

Gastroparesia

Timepoint

Along first 72 hours after surgery

Method of measurement

Nausea, vomiting and volume of nasogastric tube secretions

3

Description

Arrhythmia or bradycardia

Timepoint

Along 72 hours after surgery

Method of measurement

Electrocardiography and cardiac monitoring

4

Description

Blood pressure

Timepoint

Every 30 minutes along 72 hours after operation

Method of measurement

Systolic and diastolic blood pressure will be measured by stethoscope and aneroid sphygmomanometer

Intervention groups

1

Description

no injection into control group during operation

Category

Placebo

2

Description

Injection of 20cc of prepared ethanol solution to each of celiac ganglions at both sides of supra-pancreatic portion of aorta.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar General Hospital

Full name of responsible person

Amir Saraee

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General Surgery Ward, Firouzgar General Hospital, Behafarin Ave. Valiasr Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Masoudreza Sohrabi

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Iran University of Medical Sciences, Shahid Hemmat Expressway.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran 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

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Full name of responsible person

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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