

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of fibrine glue on seroma formation after lymph nodes D2 dissection in gastric cancer surgery

Protocol summary

Study aim

to investigate the efficacy of fibrin glue in prevention of seroma formation in gastric cancer with D 2 dissection

Design

Phase 3 of a randomized clinical trial with a control group, single-blind

Settings and conduct

Patients with gastric cancer admitted to the cancer department of Imam Khomeini Hospital in Tehran are studied

Participants/Inclusion and exclusion criteria

all Patients with gastric cancer who are candidates for gastrectomy and are hospitalized within 1399 Exclusion criteria: 1. Patients with previous history of surgery, 2. patients who are unwilling to participate in the study, 3. patients with any established local allergy to fibrin glue, 4. patients with metastasis

Intervention groups

In this single-blind randomized clinical trial study, patients with gastric cancer who are candidates for gastrectomy are randomly divided into two groups. In 1. After lymphatic D2 dissection, .5 ml of fibrin glue will be injected into the dissected area in the intervention group. 2. The control group will not receive any injection after D2 dissection. Seroma formation in the two groups is examined and compared within 24 hours after dissection and until patients are discharged. The method of measuring seroma formation will be measuring the discharge of the drain inserted during surgery in all patients.

Main outcome variables

Seroma formation

General information

Reason for update

Acronym

TFD2

IRCT registration information

IRCT registration number: **IRCT20200710048071N1**

Registration date: **2020-08-16, 1399/05/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-16, 1399/05/26**

Update count: **0**

Registration date

2020-08-16, 1399/05/26

Registrant information

Name

Ehsanollah Rahimi movaghar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2265 9074

Email address

ehsanrm81@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of fibrine glue on seroma formation after lymph nodes D2 dissection in gastric cancer surgery

Public title

Efficacy of fibrine glue on seroma formation after lymph

nodes D2 dissection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with gastric cancer are candidates for gastrectomy, hospitalized in 1399

Exclusion criteria:

Patients with a history of surgery, patients with dissatisfaction with the study, patients with any local allergy to fibrin glue, patients in the metastatic stage of cancer

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is generated using random block generation. The block size includes 4 and 2 block. 15 blocks with size of 4 and 10 blocks with size of 2 will be generated using a computer program. The blocks will be allocated using random numbers and the allocation was concealed from the patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be one-sided blind so that patients will be completely unaware of the randomization protocol and allocation

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Imam Khomeini hospital complex-
Tehran university of medical sciences

Street address

No.62 Rahimi st, Valiasr blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1586899567

Approval date

2020-06-30, 1399/04/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.106

Health conditions studied

1

Description of health condition studied

Gastric cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

Seroma formation

Timepoint

Measurement of drainage (seroma) on a daily basis until discharge of patients

Method of measurement

Drain rate (ml / 24 hours)

Secondary outcomes

1

Description

Number of days hospitalized

Timepoint

Duration of hospitalization

Method of measurement

Days of hospitalization

Intervention groups

1

Description

Intervention group: In this group, after D2 lymphatic dissection, 0.5 ml of fibrine glue (IFABOND, Peters Surgical, Bobigny, France) is injected into the dissected area, and seroma formation is measured within 24-hours after dissection until the patient's discharge. Measurement method is based on the amount of discharge in the surgical drain of the patient placed during the surgery.

Category

Treatment - Drugs

2

Description

Control group: In this group, after D2 lymphatic dissection, not the fibrin glue nor any tissue adhesive is injected into the dissected area. similar to the intervention group the examiner measured the amount of discharge in the surgical drain.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital/Tehran university of medical sciences

Full name of responsible person

Habibollah Mahmoodzadeh

Street address

No.62 Rahimi st.Valiasr Ave,Tehran

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1586899567

Phone

+98 21 2265 9074

Email

ehsanrm81@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Sahraeian

Street address

Ghods Street, Keshavrz Blvd,

City

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Tehran

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3439123900

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ehsanollah Rahimi Movaghar

Position

Fellowship Assistant of cancer surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All research data except the patient profile can be published

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

To continue research on this topic

From where data/document is obtainable

To the main and scientific person in charge of research

What processes are involved for a request to access data/document

The email sent will be checked and the requested content will be answered if it is correct

Comments