# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 committe 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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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 Blvrd,

**City**

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**Province**

Tehran

**Postal code**

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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Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Fellowship assistant of cancer surgery

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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Tehran University of Medical Sciences

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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**