

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### The role of intra-abdominal chemotherapy in inoperable gastric cancer to change to operable tumor in case-control study about one year survival and improve quality of life

#### Protocol summary

##### Summary

The aim of this study is to investigate one year survival rate and improvement in quality of life in patients with inoperable gastric cancer whom undergo neoadjuvant intraperitoneal chemotherapy. A total of 40 patients will be recruited in this study. Twenty patients who are diagnosed as inoperable tumor at the time of operation (local invasion to pancreas or great vessels) we will insert a peritoneal dialysis catheter near the tumor to perform percutaneous intraperitoneal chemotherapy. Ten days after the initial operation, we will perform percutaneous intraperitoneal chemotherapy including: mitomycin, cisplatin and 5FU for three following days by infusion pump. We will repeat this sequence after 10 days for 3 times. Ten days after latest chemotherapy we will perform laparotomy for possible definitive procedure. Two-year survival rate will be compared between intervention and control groups.

#### General information

##### Acronym

no

##### IRCT registration information

IRCT registration number: **IRCT201107257112N1**

Registration date: **2011-10-03, 1390/07/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-10-03, 1390/07/11

##### Registrant information

###### Name

Ramin Azhough

###### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1334 1317

##### Email address

azhoughr@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Liver and Gastrointestinal Diseases Research Center in Tabriz

##### Expected recruitment start date

2011-09-16, 1390/06/25

##### Expected recruitment end date

2013-09-21, 1392/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The role of intra-abdominal chemotherapy in inoperable gastric cancer to change to operable tumor in case-control study about one year survival and improve quality of life

##### Public title

The role of intra-abdominal chemotherapy in inoperable gastric cancer to change to operable tumor

##### Purpose

Other

##### Inclusion/Exclusion criteria

Inclusion criteria: presence of criteria for diagnosis as inoperable patient including: 1-local invasion to retroperitoneal organs including: Great veins like aorta-

celiac body and solid organs like pancreas. 2 - peritoneal or omentum seeding or metastatic tumor like krukentberg tumor Exclusion criteria: presence of ascites or metastasis, old age (more than 65 years old), cachectic patients with albumin less than 3 and edema

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tabriz University Of Medical Sciences

**Street address**

Tabriz University Of Medical Sciences, Golgasht avenue, Tabriz

**City**

Tabriz

**Postal code**

5166616471

**Approval date**

2011-06-12, 1390/03/22

**Ethics committee reference number**

91306/5

**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**

One year survival

**Timepoint**

6 months after the end of trial

**Method of measurement**

Follow up the patients

**2****Description**

Quality of life

**Timepoint**

6 months after the end of trial

**Method of measurement**

Follow up the patients

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

Tumor perforation

**Timepoint**

Beginning of trial to 6 months after trial

**Method of measurement**

Follow the patients and study quality of patient's life

**2****Description**

Great vesseles perforation

**Timepoint**

Beginning of trial to 6 months after trial

**Method of measurement**

Follow the patients and study quality of patient's life

**3****Description**

Vomitting

**Timepoint**

Beginning of trial to 6 months after trial

**Method of measurement**

Follow the patients and study quality of patient's life

**4****Description**

Nausea

**Timepoint**

Beginning of trial to 6 months after trial

**Method of measurement**

Follow the patients and study quality of patient's life

**5****Description**

Intra abdominal infection

**Timepoint**

Beginning of trial to 6 months after trial

#### **Method of measurement**

Follow the patients and study quality of patient's life

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: a peritoneal dialysis catheter is inserted to around the adherence area and its distal is brought out the skin. 10 days after the operation, mitomycin -cisplatin-5 Fluorouacil will be injected from the catheter during for three consecutive days using infusion pump and then the patients will be discharged. 10 days later the laparotomy will be done to explore feasibility of removing tumor.

##### **Category**

Treatment - Other

#### **2**

##### **Description**

Control group: The abdomen will be closed without any intervention or receiving peritoneal chemotherapy.

##### **Category**

Other

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Emam reza hospital,Tabriz

###### **Full name of responsible person**

Dr. Ramin Azhough, Professor Of General Surgery

###### **Street address**

General surgery ward ,Emam reza hospital, Golghasht avenue ,Azadi avenue,Azadi avenue, Tabriz

###### **City**

Tabriz

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Liver and Gastrointestinal Diseases Research Center

###### **Full name of responsible person**

Dr.kazem Mirinezhad

###### **Street address**

Emam reza hospital,Golghasht avenue,Azadi avenue,Tabriz

###### **City**

Tabriz

###### **Grant name**

###### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Liver and Gastrointestinal Diseases Research Center

#### **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**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr. Ramin Azhough

##### **Position**

Professor Of General Surgery

##### **Other areas of specialty/work**

##### **Street address**

General surgery ward, Emam reza hospital, Golghasht avenue, Azadi avenue,Tabriz

##### **City**

Tabriz

##### **Postal code**

5166616471

##### **Phone**

+98 41 1334 1317

##### **Fax**

+98 41 1334 1317

##### **Email**

azhoughr@tbzmed.ac.ir

##### **Web page address**

### **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr. Shahryar Hashemzade

##### **Position**

Professor Of General Surgery and Thorax

##### **Other areas of specialty/work**

##### **Street address**

General surgery ward,Emam reza hospital,Golghasht avenue,Azadi avenue,Tabriz

##### **City**

Tabriz

##### **Postal code**

5166616471

##### **Phone**

+98 41 1334 1317

##### **Fax**

+98 41 1334 1317

##### **Email**

Hashemzadesh@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Ramin Azhough

**Position**

Professor Of General Surgery

**Other areas of specialty/work**

**Street address**

General surgery ward, Emam reza hospital, Golghasht  
avenue,Azadi avenue,Tabriz

**City**

Tabriz

**Postal code**

5166616471

**Phone**

+98 41 1334 1317

**Fax**

+98 41 1334 1317

**Email**

azhoughr@tbzmed.ac.ir

**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*