

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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, cis platin 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 krukberg 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 vessels 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

Vomiting

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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Professor Of General Surgery and Thorax

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