

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of neoadjuvant chemotherapy on increasing resectability in patients with locally-advanced gastric cancer

#### Protocol summary

##### Summary

Sixty patients with gastric adenocarcinoma who have locally-advanced disease will be studied during this trial. The diagnosis of gastric adenocarcinoma will be made by endoscopic biopsy and subsequent histopathological analysis. A computed tomography (CT) scan of abdomen and pelvis will be conducted for the study subjects. Presence of perigastric lymph node involvement in tumors of T2 and T3 size will be considered locally-advanced. The patients will be divided into two groups randomly. The first group will receive preoperative chemotherapy based on docetaxel, cisplatin and 5-FU regimen (Case group). This regimen will be used for 6 courses. The control group will not receive any neoadjuvant chemotherapy. A repeat abdominopelvic CT scan will be conducted for the patients of the case group to document the probable lymph node regression. All patient will undergo surgical exploration for assessment of resectability. In the case group, the operation will be conducted 6-weeks after the last chemotherapy session. The resectability of locally-advanced gastric adenocarcinoma will be compared between two groups. The analysis will be conducted by Chi-square test using SPSS 19.0 software. The frequency of lymph node shrinkage in repeat CTs of patients who received neoadjuvant chemotherapy will be described. Demographic variables and in-hospital findings were also be recorded for all patients and will be compared between case and control groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014053113736N1**

Registration date: **2014-06-02, 1393/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-06-02, 1393/03/12

##### Registrant information

###### Name

Sina Zarrintan

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1330 1116

###### Email address

zarrintans@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy, Faculty of Medicine, Tabriz University of Medical Sciences

##### Expected recruitment start date

2012-08-22, 1391/06/01

##### Expected recruitment end date

2014-04-20, 1393/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of neoadjuvant chemotherapy on increasing resectability in patients with locally-advanced gastric cancer

##### Public title

Neoadjuvant chemotherapy in gastric adenocarcinoma

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: 1) Age between 18-70 years old 2) Confirmation of gastric adenocarcinoma by endoscopic sampling and histopathological analysis 3) Confirmation of locally-advanced disease by preoperative computed tomography 4) Confirmation of resectability by preoperative computed tomography Exclusion criteria: 1) Ages older than 70 2) Gastric malignancies other than adenocarcinoma 3) Distant metastasis in preoperative assessment 4) Any contraindication to chemotherapy 5) History of previous chemotherapy 6) History of previous radiotherapy

### **Age**

From **18 years** old to **70 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double 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**

Golgasht St. Tabriz University

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2012-06-19, 1391/03/30

#### **Ethics committee reference number**

524-9336

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Gastric adenocarcinoma

### **ICD-10 code**

C16

### **ICD-10 code description**

Malignant neoplasm of stomach

## **Primary outcomes**

### 1

#### **Description**

Resectability

#### **Timepoint**

Intraoperative (After chemotherapy in case group and after diagnosis in control group)

#### **Method of measurement**

Intraoperative findings

## **Secondary outcomes**

### 1

#### **Description**

Local lymph node regression

#### **Timepoint**

After neoadjuvant chemotherapy (6 weeks)

#### **Method of measurement**

Computed tomography

## **Intervention groups**

### 1

#### **Description**

Control group: Surgical exploration without neoadjuvant chemotherapy

#### **Category**

Treatment - Surgery

### 2

#### **Description**

Intervention Group Neoadjuvant chemotherapy: - docetaxel 75 mg/m<sup>2</sup>, IV, 1 hour infusion, day 1 - cisplatin 75 mg/m<sup>2</sup>, IV, 2hour infusion, day 1 - 5 FU 750 mg/m<sup>2</sup>/day, IV continuous infusion, days 1-5 Will be repeat every 3 weeks for 6 courses Surgical exploration 6 weeks after the last course of chemotherapy

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Tabriz University of Medical Sciences

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

Dr. Shahriyar Hashemzadeh

##### **Street address**

Imam Reza Hospital, Golgasht St.

**City**

Tabriz

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Jafar Soleimanpour

**Street address**

Imam Reza Hospital, Golgasht St.

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz 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**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Shahriyar Hashemzadeh

**Position**

Professor of General and Thoracic Surgery/ MD

**Other areas of specialty/work**

**Street address**

Imam Reza Hospital, Golgasht St.

**City**

Tabriz

**Postal code**

51664

**Phone**

+98 41 1334 1317

**Fax**

+98 41 1334 1317

**Email**

shahriar\_90@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Shahriyar Hashemzadeh

**Position**

Professor of General and Thoracic Surgery/ MD

**Other areas of specialty/work**

**Street address**

Imam Reza Hospital, Golgasht St.

**City**

Tabriz

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51664

**Phone**

+98 41 1334 1317

**Fax**

+98 41 1334 1317

**Email**

shahriar\_90@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Sina Zarrintan

**Position**

Resident of General Surgery

**Other areas of specialty/work**

**Street address**

Imam Reza Hospital, Golgasht St.

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1330 1116

**Fax**

+98 41 1333 4244

**Email**

s.zarrintan@yahoo.com

**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*

