

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of modify Doxotel, Cisplatin, 5fluoracil versus Eloxatin chemotherapy regimens in terms of overall survival and progression free survival in patients with advanced gastric and gastroesophageal junction cancer

Protocol summary

Summary

(1)Objective ;Comparison of modify Doxotel, Cisplatin, 5fluoracil versus Eloxatin chemotherapy regimens in terms of overall survival and progression (2)Design ;Study double blind, randomized.180 patient select and entire to both groups 80 patients.(3)Setting and conduct ;one group Use Doxotel , Cisplatin, 5Fluoracil and another group Eloxatin.(4)participants including major eligibility criteria; inclusion criteria : female and male; 18 to 65 years;Functional state ; criteria document histological for gastric and gasttoeroesophageal Junction adenocarcinoma; patients with unsurgery ; exclusive criteria : peripheral neuropathy; cerebro vascular disease; Myocardial infarction; Pulmonary trombo emboly ; unstable angina ; uncotrol infections; lactation and pregnancy; lower limb arthritis; therapy with phenytoein; (5)main outcome measures; complete remission and partial remission and progress disease and fixed disease calculation and recorded . Than fallow up for side effects of chemotherapy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062134670N1**

Registration date: **2017-08-07, 1396/05/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-07, 1396/05/16

Registrant information

Name

Mahin Soleimani

Name of organization / entity

University of Medical Center Jondy Shapor of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3013

Email address

soleimani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Jondy Shapor University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of modify Doxotel, Cisplatin, 5fluoracil versus Eloxatin chemotherapy regimens in terms of overall survival and progression free survival in patients with advanced gastric and gastroesophageal junction cancer

Public title

compararison both type chemothrapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion major eligibility criteria : female and male ;18 until 65 years; functional class; critria for histology of adenocarcinoma gastric and Gastroesophageal junction; not finding for family geoghratic psyicatric state with effect for ejucation; exclusion major eligibility criteria : peripheral nouroopathy ; Cerebrovascular disease ;Myocardial infarction ; Pulmonary thrombo emboly ; unstable angina ; uncontrol infection ; pregnancy and lactation ; previce medication for adenocarcinoma; lower limd artritic ; thyapy with phenytoin; known malignancy;

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **180**

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**

Jondy Shapor University of Medical Sciences of ethics committee

Street address

Golestan Street, Ahvaz

City

Ahvaz

Postal code**Approval date**

2017-02-25, 1395/12/07

Ethics committee reference number

Ir.ajums.rec.1395.763

Health conditions studied**1****Description of health condition studied**

Neoplasm

ICD-10 code

C15-C26

ICD-10 code description

Malignant neoplasms of digestive organ

Primary outcomes**1****Description**

Progression free survival

Timepoint

To month

Method of measurement

From start chemotherapy to last follow up or recovery

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

Overall survival

Timepoint

To month

Method of measurement

From start chemotherapy to last follow up or partial recovery

Intervention groups**1****Description**

In one group, use chemotherapy to Eloxatin with 130 mg/m2 intravenous for two hours and Epirubicin 50 mg/m2 bolus intravenous and Capecitabine 625 mg/m2 for two days for eight cycles

Category

Treatment - Drugs

2**Description**

Two groups use chemotherapy with Docetaxel 40mg/m2 intravenous infusion and Cisplatin 40 mg/m2 intravenous infusion and 5-fluorauacil 400 mg/m2 intravenous infusion for four days for eight cycles

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shafa Hospital

Full name of responsible person

Jondy Shapor University of Medical Sciences

Street address

Shafa Hospital, Golestan Street,

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Jondy Shapor University of Medical Sciences

Full name of responsible person

Dianat mohamad

Street address

Vice chancellor for research, Jondy Shapor University of Medical Sciences, Golestan Street,

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research , Jondy Shapor 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

Master of Jondy Shapor University of Medical Sciences

Full name of responsible person

Physician Ahmad Ahmadzadeh

Position

Hematologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Mahin Soleimani

Position

Resident

Other areas of specialty/work

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Person responsible for updating data

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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