Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Response Evaluation of Muscle-Invasive Bladder Cancer treated With Concomitant Chemoradiation By Either Irradiation Plus Weekly Cisplatin Or Irradiation Plus Low Dose Gemcitabine By Conventional Fractionated Radiotherapy

Protocol summary

Summary

The purpose of this study is to compare low dose Gemcitabine with Cisplatin in combined modality (CMT) for preserving the bladder in muscle invasive bladder cancer. In this study potential candidates of bladder preservation with unifocal small tumors and good bladder reserve and acceptable kidney function are randomly divided into two groups receiving Gemcitabine (27 mg / m2 twice a week) or Cisplatin (40 mg / m2 weekly) and conventional fractionated radiotherapy in the induction phase. If a pathological complete response is achieved, patients enter the consolidation chemoradiation phase and continue with the same chemotherapy regimen of Cisplatin or Gemcitabine; Otherwise patients are referred for radical cystectomy. This study compares two regimens of chemotherapy combined with radiation therapy. Response to induction treatment are compared in two groups. The aim of this study is to compare the two regimens in terms of response to treatment, possibility of surgery for bladder preservation, toxicity and tolerance of treatment. Secondary end point is comparing disease free survival of the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040332913N2**
Registration date: **2017-06-25, 1396/04/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Iran University of Medical Sciences

Expected recruitment start date
2017-06-22, 1396/04/01
Expected recruitment end date
2020-06-21, 1399/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Response Evaluation of Muscle-Invasive Bladder Cancer treated With Concomitant Chemoradiation By Either Irradiation Plus Weekly Cisplatin Or Irradiation Plus Low Dose Gemcitabine By Conventional Fractionated Radiotherapy

Public title
Response evaluation of muscle-invasive bladder cancer treated with radiotherapy and chemotherapy with Cisplatin or Gemcitabine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Primary carcinoma of the bladder (Transitional Cell Cancer) with muscularis propria invasion diagnosed within 8 weeks of registration; clinical stage T2-T4a, Nx or N0, M0 without hydronephrosis; the patient can tolerate systemic chemotherapy combined with pelvic radiotherapy and a radical cystectomy by joint agreement of the Urologist and Oncologist; The following laboratory tests that has been done within 4 weeks prior to registration on this study is as following: WBC greater than or equal to 4000, ANC greater than or equal to 1800, Hemoglobin greater than or equal to 10.0, Platelets greater than or equal to 100,000, Creatinine clearance greater than or equal to 60ml/min, Serum creatinine of 1.5 or less, If no, the creatinine clearance is greater than 60 ml/min and serum creatinine is no more than 1.8 Serum bilirubin of less than or equal to 2.0 mg%; No evidence of distant metastases, The patient has not received prior pelvic radiation therapy or chemotherapy, nor had cancers other than non-melanoma skin cancer and early stage cancer of prostate or cervix; the patient has none of any of the severe, active co-morbidities defined as following: Unstable angina and/or congestive heart failure, requiring hospitalization within the last 6 months, transmural myocardial infarction within the last 6 months, acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration, chronic obstructive pulmonary disease exacerbation or other respiratory illness requiring hospitalization or precluding study therapy at the time of registration; hepatic insufficiency resulting in clinical jaundice and/or coagulation defects; acquired immune deficiency syndrome (AIDS) based upon current CDC definition; The patient has no known severe sensitivity reactions to the drugs used in the trial.
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Two-arm randomized phase 2 trial

Secondary Ids

1

Registry name
Iran University of Medical Sciences Research management system
Secondary trial Id
95-04-143-29832
Registration date
2016-12-10, 1395/09/20

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Hemmat Highway
City
Tehran
Postal code
Approval date
2017-03-08, 1395/12/18
Ethics committee reference number
IR.IUMS.REC 1395.95-04-143-29832

Health conditions studied

1

Description of health condition studied
Transitional Cell Carcinoma of bladder
ICD-10 code
C67
ICD-10 code description
Malignant neoplasm of bladder

Primary outcomes

1

Description
Response to treatment
Timepoint
seven to eight weeks after initiation of induction treatment
Method of measurement
Cystoscopy biopsy and pathological review

Secondary outcomes

1

Description
Disease Free Survival

Timepoint
Every 3 months for 2 years
Method of measurement
Follow-up with history, physical examination, scans and urine and blood tests.

Intervention groups

1

Description
Group 1: Intravenous infusion of Gemcitabine (AQVIDA) 27 mg/m2 in 500 cc normal saline infused in 30 minutes on days 1, 4, 8, 11, 15, 18, 22, 25 of induction phase and days 1, 4, 8, 11, 15 of consolidation phase (if complete response to induction phase has achieved) with daily doses (2 Gy/Fr) of 3D- conformal conventional fractionated radiotherapy.
Category
Treatment - Drugs

2

Description
Group 2: Intravenous infusion of Cisplatin (EBEWE) 40 mg/m2 weekly in 30 minutes in 500 cc normal salineon on days 1, 8, 15, 22, in induction phase and days 1, 8, 15 in consolidation phase (if complete response to induction phase is achieved), with daily doses (2Gy/Fr) of 3D- conformal conventional fractionated radiotherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Dr Hoda Mahdavi
Street address
Firoozgar hospital, Beh Afarin st., Karimkhan-e- Zand St., Vali e Asr Sq., Tehran
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2

Recruitment center
Name of recruitment center
Shohadaye haftome-e-Tir Hospital
Full name of responsible person
Dr Baharak Keyvan
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Rajaei Expy, Shahre-Rey
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3

Recruitment center
Name of recruitment center
Emam khomeini Hospital
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Parsa Nikoofar
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4

Recruitment center
Name of recruitment center
Shahid Hashemi nedjad Hospital
Full name of responsible person
Dr Arefpour
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Vali-Nedjad Allay, Vali-e--Asr st.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research of Iran University of Medical Sciences
Full name of responsible person
Ali Javad Mousavi
Street address
Hemmat highway, Iran University of Medical Sciences, Headquarters building
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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 of Iran 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

Iran University of Medical Sciences

Full name of responsible person

Baharak Keivan

Position

Radiotherapy Oncology resident

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