Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Assessment of Tolerability, Response and Complications of Capecitabin added to Cisplatine for Concurrent Chemoradiation of Muscle Invasive Bladder Cancer

Protocol summary

Study aim

Determination of tolerability, Response and Complications of Capecitabin added to Cisplatine for Concurrent Chemoradiation of Muscle Invasive Bladder Cancer

Design

Patients with muscle invasive bladder cancer (T2 to T4a) TCC pathology Referred by an urologist for concurrent chemoradiation of bladder cancer. Based on the formula for calculating the estimated prevalence of a variable (tolerability of treatment) in a sample with an acceptable difference from the prevalence in the community (patients who endured the treatment, according to the study of RTOG 95-06, in which in 81% the treatment was completed. Approximately 23 patients would be required, including 10% falling out it would be about 25 patients. This study will be performed as a non-randomized and single-arm, phase 1-2 clinical trial.

Settings and conduct

25 patients with TCC, stage T2-T4a, first undergo the resection of the tumor as far as possible by the transuretral resection method.The patients would be irradate to the total dose of 66 Gy in 33 fractions. Concurrently Cisplatin and Capecitabine. During the treatment Lab. Data would be checked weekly and The standard questionnaire CTCAE4.03 2010 would be filled. Three months later, cystoscopy and biopsy from the tumor bed and urine cytology would be repeated.

Participants/Inclusion and exclusion criteria

Patients with muscle invasive bladder cancer (T2 to T4a) TCC pathology; patient's refusal of radical cystectomy or not being candidate to do that due to medical comorbidities referred by an urologist for concurrent chemoradiation of bladder cancer

Intervention groups

Prescribing Capecitabine in combination with Cisplatin in concurrent chemoradiation in muscle invasive bladder cancer

Main outcome variables

Determination of tolerability and course completeness of Capecitabin added to Cisplatine for concurrent chemoradiation of muscle invasive bladder cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180815040801N1**
Registration date: **2019-02-06, 1397/11/17**
Registration timing: **retrospective**

Last update: **2019-02-06, 1397/11/17**
Update count: **0**

Registration date

2019-02-06, 1397/11/17

Registrant information

Name

Peiman Haddad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2567

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-20, 1396/10/30

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of Tolerability, Response and Complications of Capecitabin added to Cisplatine for Concurrent Chemoradiation of Muscle Invasive Bladder Cancer

Public title
The Effect of Capecitabine and Cisplatin as a Radiosensitizer in Radiation of Bladder Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with muscle invasive bladder cancer (T2 to T4a) TCC pathology Patient's refusal of radical cystectomy or not being candidate to do that due to medical comorbidities Referred by an urologist for concurrent chemoradiation of bladder cancer
Exclusion criteria:
Hydronephrosis that does not resolve with usual treatments Lymphatic or distant metastasis Cr>2 GFR <30 WBC<3000 PLT<80,000
Age
No age limit
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **25**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Imam khomeini Hospital, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2018-01-15, 1396/10/25
Ethics committee reference number
IR.TUMS.IKHC.REC.1396.4240

Health conditions studied

1

Description of health condition studied
Bladder cancer
ICD-10 code
C67.9
ICD-10 code description
Malignant neoplasm of bladder, unspecified

Primary outcomes

1

Description
The amount of treatment tolerability and completion in adding capecitabine to cisplatin in comoradiation of muscle invasive bladder cancer
Timepoint
Weekly during treatment and three months after termination of the treatment
Method of measurement
CTCAE 4.03 2010 (Common Terminology Criteria for Adverse Events)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with muscle invasive bladder cancer at T2-T4aN0M0 stage referring to Department of Radiation Oncology Cancer Institute. In this study, 25 patients with Transitional Cell Carcinoma (TCC), stage T2-T4a who are candidates for radical cystectomy but refuse the surgery would be evaluated. First, the urologist resect the tumor as far as possible by the transuretral resection method, and then refer the patient for chemoradiation. For all the patients the standard questionnaire CTCAE4.03 2010 would be filled . The patients would be CT simulated and contoured. Then the best plan would be chosen according to contouring with the total dose of 66 Gy in 33 fractions. Concurrently Cisplatin 35 mg per m2 weekly and Capecitabine 625 mg

per m2 twice a day except holidays would be prescribed. During the treatment CBC, Diff, BUN, Cr would be checked weekly. The standard questionnaire CTCAE4.03 2010 would be filled weekly, last day of radiation and 3 months after the treatmant. Three months after the end of the treatment, cystoscopy and biopsy from the tumor bed and urine cytology would be repeated. Complete clinical response is defined as the absence of a tumor in the cystoscopy, a negative biopsy of the tumor site and the absence of cells Tumor in urine cytology

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Radiation Oncology Department of Imam khomeini Hospital

Full name of responsible person
Sara Soltanzadeh

Street address
Radiation oncology Research Center, Cancer Institute, Imam Khomeini Hospital, Keshavarz Ave., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Resarch assistance of Tehran University (Dr. Mohammadali Sahraian)

Street address
Vice-chancellor of research of Tehran university, Tehran University of medical sciences, Ghods St, Keshavarz Blvd. Tehran

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research@ut.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Sara Soltanzadeh

Position
Resident of Radiation Oncology

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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Radiation oncology Research Center, Cancer Institute, Imam Khomeini Hospital, Keshavarz Ave., Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Professor of Radiation Oncology

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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Data of other research maybe become at risk

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The report of study will be released.

When the data will become available and for how long
It will be after publishing the paper.

To whom data/document is available
The results will be accessible for all.

Under which criteria data/document could be used
To administer in clinical decision making the results will be accessible.

From where data/document is obtainable
To receive the results contact to correspondent.

What processes are involved for a request to access data/document
To receive the results contact to correspondent.

Comments