

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluating The Effects of Nano-Curcumin On Adverse Effects And Response Of Neoadjuvant Chemotherapy In Bladder Cancer Patients

Protocol summary

Study aim

Evaluating the effects of nano-curcumin on adverse effects and response of neoadjuvant chemotherapy in bladder cancer patients

Design

randomized, double-blind, placebo-controlled design pilot study

Settings and conduct

this trial is conducted at Shoda-e-tajrish hospital. Whereas patients and physicians allocated to the intervention group are kept blinded to the allocation, outcome assessors and data analysts are aware of the allocation arm."

Participants/Inclusion and exclusion criteria

patients with histologically confirmed muscle-invasive urothelial cell carcinoma of the bladder ECOG performance status of 0 or 1 Evidence of lymph node (N+) or distant metastasis (M1) in the screening imaging assessment

Intervention groups

Patients were randomly assigned to receive either chemotherapy without (arm A) or with NanoCurcumin (arm B). Arm A patients were administered gemcitabine (1000 mg/m², intravenous, 30 min) on days 1 and 8, every 21 days. Following gemcitabine administration, patients with a creatinine clearance 60 ml/min/m² received cisplatin every 21 days (70 mg/m², 60 min) whereas those with a creatinine clearance <60 ml/min/m² received carboplatin (AUC = 5, IV over 30 min) on day 1 every 21 days. Carboplatin doses were adjusted for renal function as per label using the Cockcroft-Gault formula and withheld in cases of significant renal deterioration. Patients in group B received the same protocol in combination with SinaCurcumin oral capsules (Exir Nano, Tehran, Iran) SinaCurcumin is a registered product from curcuminoids in Iran (IRC: 1228225765). Each soft gelatin capsule of SinaCurcumin contains 80 mg curcuminoids as nanomicelles.

Main outcome variables

clinical complete response; chemotherapy associated hematologic adverse events chemotherapy associated renal adverse events

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180226038875N1**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **retrospective**

Last update: **2019-03-06, 1397/12/15**

Update count: **1**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Saleh sandoughdaran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6647 5941

Email address

sandoughdaran@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2018-02-20, 1396/12/01

Trial completion date

2018-04-22, 1397/02/02

Scientific title

Evaluating The Effects of Nano-Curcumin On Adverse Effects And Response Of Neoadjuvant Chemotherapy In Bladder Cancer Patients

Public title

Effect of Nano-Curcumin On Neoadjuvant Chemotherapy of Bladder Cancer Patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with TCC of Bladder ECOG performance of 0 or 1 candidate to receive neoadjuvant chemotherapy

Exclusion criteria:

Metastatic disease age under 18 or over 80

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **24**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

A web-based randomized form was prepared using random permuted-block randomization technique. patient allocation was done according to the randomized list.

Blinding (investigator's opinion)

Double blinded

Blinding description

all participants and investigators including physicians were blinded. allocation of patients was based on a randomized list and patients received curcumin and placebo in a similar package.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2017-07-11, 1396/04/20

Ethics committee reference number

IR.SBMU.MSP.REC.1396.227

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

Bladder Cancer

ICD-10 code

C67

ICD-10 code description

Malignant neoplasm of bladder

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

Clinical complete response to chemotherapy

Timepoint

4 weeks after completion of chemotherapy

Method of measurement

cystoscopy

Secondary outcomes

empty

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

Intervention group: Nanocurcumin 80 mg capsules manufactured by Exir Nano Sina are taken by patients two times daily for 12 weeks during chemotherapy

Category

Treatment - Drugs

2**Description**

Control group: Placebo capsules manufactured by Exir

Nano Sina which contains starch are taken by patients two times daily for 12 weeks during chemotherapy

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
saleh sandoughdaran

Street address
Shohadaye Tajrish Hospital, Tajrish Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Saleh Sandoughdaran

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Person responsible for updating data

Contact

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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

There is no further information

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

No - There is not 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