

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Study of extremely low frequency electromagnetic effect on bladder tumor response with stage II, III, IV and status of T2 - T3A to chemo radiotherapy

Protocol summary

Summary

Objectives: The aim of this study is to use electromagnetic waves along with chemo radiotherapy treatment to increase the permeability of tumor cells to chemical drugs In order to increase the efficiency of drug for destroying tumor and also enhance the output of treatment. On the other hand this measure reduce the time of treatment duration and side effects of treatment factors. **Design:** The type of this research was determined to be case- study (interventional). In this study chemo radiotherapy method plus electromagnetic waves with very low frequency (1Hz) will be used for treating bladder cancer. **Setting and conduct:** After each stage of chemotherapy, patients are exposed to repetitive trans cranial magnetic stimulation device (RTMS) for 30 seconds and receive 30 pulses 1 Hz. These pulses caused the cell's pores be opened and drugs permeate into the tumor cells easily to destroy them. **Inclusion criteria:** Patients with bladder cancer in grades 2, 3, 4 and stage T2 to T3A, without cystectomy, patients with heart and respiratory problem and etc that are not candidate to be surgically operated or patients who want to maintain their bladder. **Exclusion criteria:** Patients are in stages T1 and T4, patients with creatinine > 1.5, patients don't have proper physical ability clinically (performance status>2) and patients with severe leukopenia or with lack of therapy tolerance. **Intervention:** Electromagnetic waves, chemo radiotherapy **Main outcome measures (variables):** Tumor grade, drug dose, radiation dose, old, sex.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011312124N1**
Registration date: **2013-04-21, 1392/02/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

Name

Sadegh Dehghani

Name of organization / entity

Shahid Beheshti medical sciences univesity

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 5814

Email address

s.dehghani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Cancer Research Center of Shahid Beheshti University of Medical Sciences Urology Nephrology Research Center of Shahid Beheshti University of Medical Sciences Vice chancellor for research of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-02-18, 1391/11/30

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of extremely low frequency electromagnetic effect on bladder tumor response with stage II, III, IV and status of T2 - T3A to chemo radiotherapy

Public title

The use of very low frequency electromagnetic waves with radiotherapy and chemotherapy for treating bladder tumors.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with bladder cancer; Patients without cholecystectomy; Patients with heart, lung problem and... are not candidates for surgery; Patients who are in grades 2, 3, 4 and stage T2 to T3A. Exclusion criteria: Creatinine > 1.5; Patients don't have physical ability clinically (performance status > 2); Patients who are in stage T1 and T4; Patients because of severe leukopenia cannot tolerance the treatment.

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not 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

N#44, Next of Labbafinejad Hospital, 9th st Boostan, Pasdaran ave

City

Tehran

Postal code

Approval date

2012-03-12, 1390/12/22

Ethics committee reference number

1225/1/پ

Health conditions studied

1

Description of health condition studied

Bladder cancer

ICD-10 code

C67.0, C67

ICD-10 code description

Trigone of bladder, Dome of bladder, Lateral wall of bladder, Anterior wall of bladder, Posterior wall of bladder, Bladder neck, Ureteric orifice, Urachus, Overlapping lesion of bladder, Bladder, unspacific

Primary outcomes

1

Description

Tumor grade

Timepoint

Before of treatment

Method of measurement

Ultrasound, CT, MR, Cystectomy

2

Description

Drug dose

Timepoint

Before of treatment and during of treatment

Method of measurement

According to grade and stage of tumor

3

Description

Radiation dose

Timepoint

Before of treatment and during of treatment

Method of measurement

According to grade and stage of tumor

4

Description

Old

Timepoint

Before of treatment

Method of measurement

Patient's record or interview

5

Description

Sex

Timepoint

Before of treatment

Method of measurement

Patient's record or interview

Secondary outcomes

1

Description

Treatment side effects

Timepoint

Along of treatment

Method of measurement

Visual and blood test

2

Description

BUN, Crea, SGOT, SGPT

Timepoint

before treatment and along of treatment

Method of measurement

blood test

3

Description

Blood cells count

Timepoint

Before treatment and along of treatment

Method of measurement

Blood test

4

Description

Tumor size

Timepoint

Before treatment and middle of treatment and end of treatment

Method of measurement

Ultrasound, CT, MRI, Cystectomy

Intervention groups

1

Description

The use of RTMS device for generating electromagnetic waves with frequency 1HZ in the intervention group

Category

Treatment - Other

2

Description

The use of RTMS device while it is turn off in control group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy department of Shohada Tajrish hospital

Full name of responsible person

Dr Bahram Mofid

Street address

Shohada Tajrish Hospital, Tajrish

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cancer Research Center of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Esmaeil Akbari

Street address

Cancer Research Center of Shahid Beheshti University of Medical Sciences, Shohadaye Tajrish Hospital, Tajrish Sq

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cancer Research Center of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Urology Nefrology Research Center of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Naser Shakhse Salim

Street address

N#44, Next of Labbafinejad Hospital, 9th st Boostan, Pasdaran ave

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Urology Nephrology Research Center of Shahid Beheshti
University of Medical Sciences

Proportion provided by this source**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

3**Sponsor****Name of organization / entity**

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Doctor Mohammad Rahmati Roodsari

Street address

Shahid Beheshti University of Medical Sciences, Next
of Taleghani Hospital, Parvaneh st, Yaman st, Shahid
Chamran Highway

City

Tehran

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, Shahid Beheshti University
of Medical Sciences

Proportion provided by this source**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**

Urology Nephrology Research Center

Full name of responsible person

Doctor Bahram Mofid

Position

Oncologist

Other areas of specialty/work**Street address**

Radiotherapy Department, Shohada Tajrish Hospital,
Tajrish

City

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sadegh Dehghani

Position

M.Sc in Radiobiology

Other areas of specialty/work**Street address**

Dorm N. 21, Shahid Ghazvini Alley, North Felestin St,
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Tehran

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Fax**Email**

dehghan907@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sadegh Dehghani

Position

M.Sc.in Radiobiology

Other areas of specialty/work**Street address**

Dorm N. 21, Shahid Ghazvini Alley, North Felestin St,
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City

Tehran

Postal code**Phone**

+98 21 8898 5814

Fax**Email**

dehghan907@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
Data Dictionary
empty