Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial to evaluate using electroporation system for treatment purposes and drug delivery to the tumor

Protocol summary

Study aim
Achieving optimized parameters for cancer treatment by electroporation method

Design
Patients are referred individually by specialist physicians according to the stated criteria for admission to the study and are treated by placing one or more needles around the tumor and stimulating the electroporation method. 40 patients are now ready to receive treatment in the hospital. Patients are aware of their treatment and the study is not capable of blinding.

Settings and conduct
After introducing the patient to this research and obtaining informed consent according to the patient's medical records and the location and type of tumor, the treatment protocol and the choice of reversible electroporation or electrochemotherapy should be selected. Then the type of electrodes, the number of stimulation doses of the drug required for complete treatment of the tumor is calculated. Then the electrodes are placed around the tumor and stimulation is performed according to the performed calculations.

Participants/Inclusion and exclusion criteria
Eligibility criteria: • Radiological based on cancer in Stages IA, IB, IIA, IIB, IIIA, IIIB, IV • Good performance (Karnofsky Score ≥ 70) • Life expectancy of at least 3 months Exclusion criteria: • Pregnancy Coagulation disorder (INR more than 1.5 times control) • Platelets less than 100,000 • Anemia (hemoglobin less than 10) • Serious acute infection • Having an implanted pacemaker, defibrillator or deep brain stimulator or heart arrhythmias.

Intervention groups
1) The intervention group received electroporation in addition to the usual treatment 2) control group with usual treatment

Main outcome variables
Changes of tumors' size, alteration in microscopic and pathological characteristics and IHC markers of the tumor, changes in clinical manifestations, changes of different serum markers.

General information

Reason for update

Acronym
EP

IRCT registration information
IRCT registration number: **IRCT20190904044697N8**
Registration date: **2022-10-02, 1401/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-02, 1401/07/10**
Update count: **0**

Registration date
2022-10-02, 1401/07/10

Registrant information

Name
Mohammad Abdolahad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8802 8367

Email address
m.abdolahad@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-01, 1401/07/09

Expected recruitment end date
2024-09-30, 1403/07/09

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to evaluate using electroporation system for treatment purposes and drug delivery to the tumor

Public title

Cancer treatment by electroporation method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cancer patients who have different types of cancer with solid tumors. cancer stage IA, IB, IIA, IIB, IIIA, IIIB, IV (Karnofsky Score ≥ ۷۰) Patients with different types of benign and malignant tumors

Exclusion criteria:

Pregnancy Coagulation disorder (INR more than 1.5 times control) Platelets less than 100,000 Anemia (hemoglobin less than 10) Serious acute infection Having an implanted pacemaker, defibrillator or deep brain stimulator or cardiac arrhythmias.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In the irreversible electroporation method, we only need to place one or more needles in the desired area and around the tumor, and after placing these needles, 80 to 100 pulses with a duration of 100 microseconds will be applied and finally the needles will be removed. In the reversible electroporation method, the chemotherapy drug, whose dosage and possibility of use have been checked before, is injected as IT or IV. 5 to 15 minutes after drug injection, it will be possible to apply stimulation, so during this time, we will place the electrodes in the right place and after this time, we will apply electrical pulses. Applying the pulse increases the permeability of the cell membrane and the cell will receive a much higher dose than usual. For example, according to reports, the penetration of bleomycin has increased up to 5000 times.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of Imam Khomeini hospital complex-Tehran University of Medical Sciences

Street address

North Amirabad - North Kargar Street - Above Jalal Al Ahmad Blvd - Opposite 9th Alley - Technical Faculty of Tehran University - Old building of Faculty of Electrical Engineering - Nanobioelectronics Laboratory

City

Tehran

Province

Tehran

Postal code

۵۱۵-۱۴۳۹۵

Approval date

2022-08-30, 1401/06/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.125

Health conditions studied

1

Description of health condition studied

Malignant cancer with solid tumor

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

2

Description of health condition studied

Benign tumor with solid mass

ICD-10 code

D24

ICD-10 code description

Benign neoplasm of breast

3

Description of health condition studied

Malignant cancer with solid tumor

ICD-10 code

C22

ICD-10 code description

Malignant neoplasm of liver and intrahepatic bile ducts

4

Description of health condition studied

Benign tumor with solid mass

ICD-10 code

D13.4
ICD-10 code description
Benign neoplasm of liver

5

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C77
ICD-10 code description
Secondary and unspecified malignant neoplasm of lymph nodes

6

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C78.0
ICD-10 code description
Secondary malignant neoplasm of lung

7

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C79.2
ICD-10 code description
Secondary malignant neoplasm of skin

8

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C73
ICD-10 code description
Malignant neoplasm of thyroid gland

9

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C56
ICD-10 code description
Malignant neoplasm of ovary

10

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C48
ICD-10 code description
Malignant neoplasm of retroperitoneum and peritoneum

11

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C22.1
ICD-10 code description
Intrahepatic bile duct carcinoma

12

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

13

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C15
ICD-10 code description
Malignant neoplasm of esophagus

Primary outcomes

1

Description
tumor size
Timepoint
Every two weeks
Method of measurement
Imaging modalities (Conventional ultrasound and especially Doppler ultrasound, MRI and CT scan)

2

Description
Clinical and quality of life changes
Timepoint
Every week
Method of measurement
Investigating of Clinical Manifestation

3

Description
Tumor cell death
Timepoint
every three month
Method of measurement
Immunostaining, Immunohistochemistry, H&E

4

Description
Metastasis to other organs
Timepoint
Every 6 month
Method of measurement
Imaging by MRI, CT or PET scan

Secondary outcomes

1

Description
Quality Of Life
Timepoint
90 days
Method of measurement
Questionnaire about quality of life indicators based on EORTC QLQ-C30

Intervention groups

1

Description
ABC Intervention group: Receiving electroporation in addition to the usual treatment. Definition of intervention: In cases where the tumor is inoperable, the patient will be assigned in the intervention group and will be treated with electroporation technique under the supervision of the surgeon in the following two cases: 1) Tumor through the skin can receive the electroporation technique and does not require open surgery. 2) In order to reach the tumor site, before receiving the electroporation technique, surgery should be performed to access the tumor and then the technique should be performed for the patient during the operation. In each treatment group, the patients received bleomycin with a dose of 1000 IU/ml and manufactured by the company. BDR Pharmaceuticals India and intravenously or intratumorally, eight minutes before electroporation. Then, electric pulses are inserted into the tumoral tissue through electrodes made of 316 stainless steel, which are biocompatible and have a medical grade, and with a thickness of 300 micrometers, which are either needles or plates, depending on the size of the tumor and the discretion of the study leader. Establishing electric pulses with a field intensity of 100 V/cm to 2000 V/cm and with a width of 1 to 100 microseconds and an alternating number of pulses will create holes in the cell membrane to increase the permeability of bleomycin. The pulse generating device is made in Iran by Nano Hesgarsazan Salamat Arya Company.
Category
Treatment - Devices

2

Description
Control group: In this group, patients receive only the standard and routine treatment prescribed by a specialist doctor.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Abdolahad
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
tehran
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Postal code
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Phone
+98 21 2282 4069
Email
m.abdolahad@ut.ac.ir
Web page address

2

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Mohammad Abdolahad
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Tajrish Square - Tajrish Martyrs Hospital
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19899 34148
Phone
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Email
m.abdolahad@ut.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Nano Fund
Full name of responsible person
Dr Mohammad Hosein Bahreini
Street address
No. 38, West Nastaran Ave (Arab), Khorramshahr St., North Sohrevardi St., Tehran
City
Tehran
Province
Tehran
Postal code
1533984611
Phone
+98 21 8876 9188
Email
info@nanofund.ir
Web page address

http://nanofund.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran Nano Fund

Proportion provided by this source

70

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Abdolahad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

electrotechnical Specialist in oncosurgery and cancer therapy

Street address

Nano bio electronic lab, ground floor, school of electrical and computer engineering, university of Tehran faculty of engineering, North Kargar Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Abdolahad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

electrotechnical Specialist in oncosurgery and cancer therapy

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Abdolahad

Position

Associate professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

60% of the information about the main outcome, can be shared

When the data will become available and for how long

Available 6 months after the paper has been published.

To whom data/document is available

The data will be available for medical staff and academic institutions.

Under which criteria data/document could be used

Non-identifiable personal data will not be usable for the applicant and will only inform the patient of a positive clinical trial that the device is functioning properly

From where data/document is obtainable

Applicants can request data access via email. The data will be available to the applicant in a categorized manner with pathology reports, imaging reports and serum markers by request.

What processes are involved for a request to access data/document

The data will be sent to the applicant within two weeks after the request.

Comments