Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of local and short time treatment of superficial and visceral tumors using electrochemical method Based on a needle wire without any destructive effect for healthy tissues

Protocol summary

Study aim

The overall goal is to achieve optimized parameters for the rapid treatment of various cancers that eliminate the patients need to have surgery or other treatments such as radiotherapy, chemotherapy, etc. So that, single needle base EChT can be used as a treatment for any types of solid tumors.

Design

Patients are recommended by their specialist are treated by EChT method and inserting a needle wire into the tumor without any destructive effect for healthy tissues. We are prepared to take 40 patients at the hospital and apply EChT therapy on them. Patients are aware of their treatment.

Settings and conduct

The patients who candidate for study, hospitalize at the Noorafshar hospital. The tumors size with imaging methods, tumor markers and other serum markers is measured before the therapy. The needle electrode was inserted into the tumor and the time duration for the tumor treatment depends on the size and type of the tumor between one to three sessions and each session lasts up to one hour. After the end of the course, the sizes and blood markers are checked again and announced to the specialists.

Participants/Inclusion and exclusion criteria

Patients who have benign and malignant solid tumors with high proliferation factor

Intervention groups

Patients who are nominated according to the inclusion criteria will undergo EChT treatment. A wire needle is inserted into the tumor and by electrolysis resulting from direct DC current, it causes ionic and pH changes in the tumor tissue. Consequently, leads to changes in the tumor microenvironment and the destruction of cancer cells. The size of the tumors are compared with the ones which are outside of the electrode's area.

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 and electrolytes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190904044697N5**
Registration date: **2020-04-17, 1399/01/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-17, 1399/01/29**
Update count: **0**

Registration date

2020-04-17, 1399/01/29

Registrant information

Name

Mohammad Abdolahad

Name of organization / entity

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Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2021-03-20, 1399/12/30

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

Scientific title
Clinical trial of local and short time treatment of superficial and visceral tumors using electrochemical method Based on a needle wire without any destructive effect for healthy tissues

Public title
Safe and short time treatment of superficial and unresectable deep tumors
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Cancer patients who have different types of cancer with solid tumors. Patients who the biopsy results of their tumors approved that the tumors are malignant Patients with any superficial and unresectable deep tumors Patients with highest levels of invasion are more appropriate for receiving treatment (i.e. triple negative breast cancer and gastrointestinal invasive cancers) Pathological or radiological evidence of progression of the disease despite common treatments Patients with end-stage cancer who oncologists confirm that they did not profit from an alternative treatment, can include the study as a palliative therapy Patients with different types of benign and malignant tumors
Exclusion criteria:
Patients who do not have a definable and discriminating mass to evaluate response to treatment. pregnancy Patients who do not have appropriate general condition and need intensive care.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
In patients who have at least 2 tumors which have appropriate distance from each other, one of them are treated (intervention) and the other one consider as control to evaluate the effectiveness of the treatment
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 China and Germany, Electrochemical therapy (EChT) is considered an effective complementary treatment for cancer patients who do not respond well to surgery, chemotherapy, and radiotherapy. In this treatment, depending on the tumor size, only one to three sessions of the treatment process are performed, and there is no need to hospitalize the patient during treatment. This method has the least reported side effects compared to other treatments. In EChT, tissue electrolysis involves placing two or more electrodes, with constant current, in a tumor or its adjacent causing ionic and pH changes. This causes changes in the microenvironment surrounding the tumor and the destruction of cancer cells. In fact, in this method, the destructive products resulting from the reaction formed during the electrochemical treatment of the electrodes cause immediate cell death and long-term effects on the surrounding tissues. Severe changes in pH adjacent to the electrodes cause immediate necrosis, while secondary changes, such as a decrease in tumor perfusion, cause hypoxia and a decrease in nutriment.The disadvantage of the common EChT method is its inability to treat the deep masses, due to the damage caused by DC fields from the mass area to the skin. Therefore, with the concurrent dominance regarding the electronics technology and cancer therapist's team, we decided to modify the structure and engineering of the electric fields to apply the EChT method on a needle-shaped wire for the treatment of superficial and deep masses by laparoscopic intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
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No.23, 16 Azar Ave, Tehran Ave., Tehran, Iran Postal Code: 1417863181
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Approval date
2020-03-09, 1398/12/19
Ethics committee reference number
IR.TUMS.VCR.REC.1398.1027

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

Primary outcomes

1

Description
Changes in the size and extent of tumor necrosis
Timepoint
one week
Method of measurement
Imaging modalities (Conventional ultrasound and especially Doppler ultrasound, MRI and CT scan), Immunohistochemistry, pathological and microscopical markers and cellular staining

2

Description
Clinical and quality of life changes
Timepoint
Every day
Method of measurement
Blood Test, Investigating of Clinical Manifestation

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
Intervention group: Patients with all types of benign and malignant carcinoma tumors with evaluable solid mass that were nominated in this study according to inclusion criteria will undergo electrochemical treatment. This technique uses a needle-shaped wire that consists of two back-to-back needles separated by an insulating layer and twisted-pair conductors to prevent any charge and electric field other than the needle area in the patient's body. The voltage is then applied to the electrode in the range of 5-9 volts to provide a constant current of about 5-10 mA. The amount of charges transferred depends on the size and type of tumor. In fact, in the EChT method, the destructive effects of electrolysis created by direct DC current are used, which causes ionic and pH changes in the tumor tissue. Consequently, leads to changes in the tumor microenvironment and the destruction of cancer cells. The treatment process is monitored live under the ultrasound sonography guide throughout the treatment so that any changes in vital organs and other tissues despite the tumor mass have occurred, or if there is a problem with the patient's vital signs, can be discontinued immediately, which is one of the important capabilities of this method. Also, according to pre-clinical studies, the side effects of this study were not observed. In this method, the patient is treated for a maximum of 1 hour with an electrical power of less than 90 mW and then re-examined for tumor changes.
Category
Treatment - Devices

2

Description
Control group: If patients undergoing electrochemical treatment have two or more tumors, this method could be used to treat the number of tumors, without any treatment for the rest of them. Tumors treated with EChT were considered as intervention group and untreated masses as controls. Since the therapeutic effect of this method is local and around the electrodes, these tumors are located a long distance from the needle electrode and are assumed not to receive DC current. Therefore, changes in these tumors are considered as changes in the control group.
Category
Treatment - Devices

3

Description
Control group: Patients with the same clinical and pathological condition with the patients who are candidated for electrochemical therapy. They do not receive any treatment or they receive any other treatments which is not electrostatic therapy. The changes of tumor size, serum markers and clinical manifestations are recorded during the same period of time. It is assumed that there is not a control patient for each of candidate patient with different types of cancer.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Noorafshar Hospital
Full name of responsible person
Dr Mohammad Abdolahad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Nano Fund
Full name of responsible person
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Postal code

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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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

We will send the data to the applicant in 2 weeks

Comments