Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Non-invasive localized positive electrostatic therapy of malignant cancer tumors by suppression of anti-apoptotic enzymes and expression of apoptotic ones

Protocol summary

Study aim

Non-invasive localized positive electrostatic therapy of malignant cancer tumors by suppression of anti-apoptotic enzymes and expression of apoptotic ones and investigation of its effects on malignant tumors.

Design

Patients are recommended by their specialist to enter the study and the patch of electrostatic therapy is placed on their skin. We are prepared to take 50 patients at the hospital and apply Electrostatic therapy on them. Patients are aware of their treatment.

Settings and conduct

The patients who candidate for study, hospitalize at the Noorafshar hospital. The size of the tumors, tumor markers and other serum markers is measured before the therapy. The patch is placed on the surface of the patient's skin at the nearest place to the tumor and fixes there. Patients can detach the device for personal stuffs and attach it again. They hospitalize for about 12 days and during these days vital sign is checked per 6 hours and other general assessment per 12 hours. 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 malignant solid tumors with high proliferation factor.The cells are not obey the normal cellular pathway of the tissue.

Intervention groups

We use a flexible patch which is designed by nano fabrication process, charged by DC electrical power system to produce accumulated positive charges and transfer to patients' body who candidate for study. The patch is placed on the surface of the patient's body at the nearest place to the malignant tumor. The size of the tumors are compared with the ones which are outside of the patch'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

ECT

IRCT registration information

IRCT registration number: **IRCT20190904044697N2**
Registration date: **2019-11-02, 1398/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-02, 1398/08/11**
Update count: **0**

Registration date

2019-11-02, 1398/08/11

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

2019-01-01, 1397/10/11

Expected recruitment end date

2020-01-01, 1398/10/11

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

Scientific title
Non-invasive localized positive electrostatic therapy of malignant cancer tumors by suppression of anti-apoptotic enzymes and expression of apoptotic ones

Public title
Positive Electrostatic therapy; selective destruction of cancer tumors through their attraction to positive charges
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have different types of cancer with solid tumors. Patients who the biopsy of their tumors approved that the tumors are malignant. Patients who their malignant tumors are not obey the normal cellular pathways of the tissue. Patients with malignant tumors and highest levels of invasion are more appropriate for receiving treatment (i.e. triple negative breast cancer). Patients who their tumors are not too deep and not too far from the surface of the body. Pathological or radiological evidence of malignancy Pathological or radiological evidence of progression of the disease despite classical treatments Pathological or radiological evidence of recurrence of the disease despite classical treatments At least 3 months life expectency 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.
Exclusion criteria:
Patients who do not have appropriate general condition and need intensive care. Patients with tumors which tumor cells are obey the normal cellular pathways of the tissue. Patients who have different types of cancer which have no solid tumors. Patients with benign tumors or the types of malignant tumors which are not invasive enough. Patients who their tumors are deep and far from the surface of the skin. Coagulation disorders (INR>1.5) Pregnancy Platelets<150000 Neutropenia (neutrophil<1500) Anemia (Hemoglobin<12) Acute Infection Patients with pacemaker or any types of cardiac arrhythmia Abnormal biochemistry or electrolyte of the serum.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **0**
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 to be the control tumor.
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
We investigated a new procedure based on positive electrostatic charges which induce S-arrest on malignant cells without any side-effects on normal regions. We used a patch charged by DC electrical power system to produce accumulated positive charges. Patches were attached on top of the skin. H&E, IHC, sonography, PET and confocal imaging were experimented to monitor the size and morphological states of the tumor. Signaling pathways activated during the electrostatic therapy were investigated by western blotting and Real-time PCR analyses.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
No.23, 16 Azar Ave, Tehran Ave., Tehran, Iran Postal Code: 1417863181
City
Tehran
Province
Tehran
Postal code
1417863181
Approval date
2018-08-18, 1397/05/27
Ethics committee reference number
IR.TUMS.VCR.REC.1397.354

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
Malignant cancer with solid tumor
ICD-10 code
C78.7
ICD-10 code description
Secondary malignant neoplasm of liver and intrahepatic bile duct

3

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

4

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

5

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

6

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

7

Description of health condition studied
Malignant cancer with solid tumor
ICD-10 code
C83.3
ICD-10 code description
Diffuse large B-cell lymphoma

8

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

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
C48.2
ICD-10 code description
Malignant neoplasm of peritoneum, unspecified

Primary outcomes

1

Description
Tumor sizes, Serum Tumor Marker, Clinical Manifestation , Pathological and microscopical features, Immunohistochemistry markers. In patients with end-stage cancer, their clinical and quality of life changes are investigated and the electrostatic therapy are considered as a palliative therapy.
Timepoint
12 days
Method of measurement
Imaging modalities, Blood Test, Investigating of Clinical Manifestation, Immunohistochemistry, pathological and microscopical markers and cellular staining

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 solid malignant tumors who are candidated to get electrostatic therapy based on inclusion criteria. We use a flexible patch which is designed by nano fabrication process, charged by DC electrical power system (30kv) to produce accumulated

positive charges and transfer to patients' body who candidate for study. The patch is placed on the surface of the patient's body at the nearest place to the malignant tumors. The patients are investigated after about 12 days of therapy and the outcome factors like the size of the tumor are perused.

Category

Treatment - Devices

2

Description

Control group: The patients who candidate for the electrostatic therapy have different tumors. Some of them are at the site of the patch and getting effect from it and some of them are outside of the patch area. The tumors which are outside of the area and assumed not to have enough electrical charge are considered as control group and the changes are measured and recorded.

Category

Treatment - Devices

3

Description

Control group: Patients with the same clinical and pathological condition with the patients who are candidated for electrostatic 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

Street address

Sadeghin Alley (17th West), Khodaverdi St, Pourebtehaj (Kashanak) St, Bahonar (Niavaran) Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1978734763

Phone

+98 21 2282 4069

Fax

+98 21 2282 4060

Email

m.abdolahad@ut.ac.ir

Web page address

https://noor-afshar.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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr 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.

City
Tehran

Province
Tehran

Postal code
1439957131

Phone
+98 21 8802 8367

Email
m.abdolahad@ut.ac.ir

Web page address
https://nbel.ut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Mohammad Abdolahad

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Cancer Specialist

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

City
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Province
Tehran

Postal code
1439957131

Phone
+98 21 8802 8367

Email
m.abdolahad@ut.ac.ir

Web page address
https://nbel.ut.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Mohammad Abdolahad

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Cancer Specialist

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

City
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Province
Tehran

Postal code
1439957131

Phone
+98 21 8802 8367

Email
m.abdolahad@ut.ac.ir

Web page address
https://nbel.ut.ac.ir

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