

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 expectancy 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

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##### Province

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##### Postal code

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##### Phone

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##### 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

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##### 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.

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**Web page address**

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## 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**

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electrical and computer engineering, university of  
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## 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**

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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**