Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Targeted drug delivery using polar or charged drugs by opposite electrostatic charge, in breast cancer clinical trial

Protocol summary

Study aim

Non-invasive and local treatment of breast tumors using targeted drug delivery with charged or water-soluble drugs and increase their uptake by opposite electrostatic charge

Design

Patients are recommended by their specialist to enter the study, and after chemotherapy started, the patch of electrostatic therapy (by opposite charge) is placed on their skin. We are prepared to admit 40 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 motamed center institute breast cancer research center. The size of the tumors, tumor markers and other serum markers is measured before and after the therapy and announce to specialist. The patch is placed on the surface of the patient's skin at the nearest place to the tumor during chemotherapy and fixes there. Patients can detach the device for personal stuffs and attach it again; during these days vital sign is checked per 6 hours and other general assessment per 12 hours.

Participants/Inclusion and exclusion criteria

Patients with breast cancer who have a distinct mass from the surrounding tissue and are candidates for chemotherapy.

Intervention groups

In this study, patients are candidate and treated for EDD according to the inclusion criteria. After injection of the polar or water-soluble drug, the flexible patch, which is made using nanotechnology and is charged by a direct current electric power supply, is placed on the surface closest to the mass on the body and fixed during chemotherapy treatment. Mass changes in the patch area are compared to out-of-area masses.

Main outcome variables

Changes of tumors' size in EDD method, 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

EDD

IRCT registration information

IRCT registration number: **IRCT20190904044697N6**
Registration date: **2020-09-14, 1399/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**
Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Mohammad Abdolahad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2020-12-29, 1399/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Targeted drug delivery using polar or charged drugs by opposite electrostatic charge, in breast cancer clinical trial

Public title

Targeted polar or charged drug delivery, using opposite electrostatic charge

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All breast cancer type patients, with different stages, by distinguished tissue biopsy to normal one which confirmed the tumor existence. Pathological or radiological evidence of tumor existence. All breast cancer patients become a chemotherapy candidate in neoadjuvant, adjutant, and post-operative circumstance. Patients who are indicated for administration polar water-soluble or charged chemotherapy drugs such as cisplatin, carboplatib, cyclophosphamide, doxorubicin

Exclusion criteria:

Patients who do not have appropriate general condition and need intensive care. Patients who have no assessable tumor for treatment evaluation. Coagulation disorders (INR>1.5) Thrombocytopenia (Platelets<150000) Anemia (Hemoglobin<12) Acute Infection Patients with pacemaker or any types of cardiac arrhythmia Abnormal biochemistry or electrolyte of the serum. Pregnancy Neutropenia (neutrophil<1500) Patients who are not receiving polar or charged chemotherapy drugs

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 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

Parallel

Other design features

after drug preparation, it will be injected by closest possible vein to the tumor. In the next step, use the patch, by opposite charge (according to the drug charge) on the target. electrostatic patch, which connected to the electrostatic source, will cause polymer transportation (due to opposite charge) to target place. As a result, by circulating the charged drug in the body and passing through the mass, the water soluble polarized drugs are affected by the electrostatic patch of opposite charge and trapped close to the patch. The drug delivered directly to the targeted tissue. In this method, by this drug up-taking mechanism, we will reduce the injection dose dramatically and avoid drug-depended side effects on other tissues and organs. H&E, IHC, sonography, PET scan and confocal imaging were experimented to monitor the size and morphological states of the tumor.

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

2020-01-31, 1398/11/11

Ethics committee reference number

IR.TUMS.VCR.REC.1398.852

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

Drug delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Accurate tumor size under patch area
Timepoint
10 days after the first, second, third, and fourth courses of chemotherapy
Method of measurement
Imaging modalities such as sonography, mamography, MRI, etc.

2

Description
Serum tumor marker
Timepoint
10 days after the first, second, third, and fourth courses of chemotherapy
Method of measurement
laboratory test on blood samples

3

Description
Clinical Manifestations
Timepoint
10 days after the first, second, third, and fourth courses of chemotherapy
Method of measurement
Accurate history taking and physical examination

4

Description
Pathological and microscopical features of the tumor
Timepoint
10 days after the first, second, third, and fourth courses of chemotherapy
Method of measurement
Biopsy taking and specific and non-specific staining of the tissue

5

Description
Immunohistochemical staining
Timepoint
10 days after the first, second, third, and fourth courses of chemotherapy
Method of measurement
Biopsy taking and specific staining of the tissue

Secondary outcomes

1

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

2

Description
evaluating long side effects of chemotherapy drugs
Timepoint
90 days
Method of measurement
history taking and physical examination

Intervention groups

1

Description
Intervention group: Patients with breast cancer with assessable solid mass are nominated according to the inclusion criteria, are treated with chemotherapy drugs and opposite electrostatic charge. The patch is made using nanotechnology and is charged with a direct current electric power supply with a voltage of 30 kV, and by accumulating the opposite charge of the charged drug on the patch, the charge is transferred to the tumor site. This flexible patch is fixed on the surface of the body at the closest site to the tumor mass. The patient is treated during chemotherapy and then re-examined for mass changes.
Category
Treatment - Devices

2

Description
Control group: The patients who candidate for the electrostatic therapy and have some tumors which are outside of the patch area and assumed not to affect enough by electrical charge, are considered as control group. Moreover, patients with the same drug and clinical and pathological condition who do not receive any EDD treatment during chemotherapy are considered as control group, too. The changes are recorded during the same period of time. It is assumed that there is not a control patient or tumor for each of participant.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Motamed Cancer Institute, Breast Cancer Center
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
Dr Mohammad Hosein Bahreini
Street address
No. 38, West Nastaran Ave (Arab), Khorramshahr St., North Sohrevardi St., Tehran
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Postal code
1533984611
Phone
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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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Tehran University of Medical Sciences
Position
Dr Mohammad Abdolahad
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

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

Breast cancer surgery

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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