

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Real-time intra-operative in-vivo diagnosis of internal margins involved to breast pre-invasive/invasive cancer cells through pathological classification using a handheld electrochemical system

Protocol summary

Study aim

Checking the surgical margins in breast cancer patients is a critical step to be ensured from safe removal of high-risk suspicious cells with minimal dissection of normal tissues. Remained neoplastic lesions inside the body, induces unavoidable re-surgery and post-surgical therapies which cause many side effects. Here we introduce a real-time intra-operative breast margin checking tool with the capability of diagnosing the pathological state of the tissues. This probe (Cancer Diagnostic Probe CDP) comprises three integrated sensing needles and an electrical readout board. We carried out the diagnosis by entering the needles in the margin tissue followed by recording and compiling the electrochemical peak data in less than 40 seconds.

Design

A pragmatic, cancer patients community-based, single group, randomized trial

Settings and conduct

Frozen and permanent are being done as a routine procedure for every patient during surgery. If a region scored positive by CDP, its adjacent should also be checked. CDP dissected samples are compared to both permanent and frozen of reciprocal external margins of the patients. During surgery, the pathologist opinion about involved external margins in the frozen section is considered as the final diagnosis.

Participants/Inclusion and exclusion criteria

We select patients from all categories of breast cancer candidate for mastectomy or lumpectomy.

Intervention groups

During breast surgery after tumor dissection, CDP checks all the internal margins and the legions checked will be dissected either scored positive or negative by CDP and will be se for permanent pathology as CDP samples.

Main outcome variables

Intra-operative, non- invasive pathological classification

of internal margins, in correlation with the metabolisms of breast cells, is the main achievement of CDP as a real-time diagnostic tool.

General information

Reason for update

Acronym

CDP, Cancer Diagnostic probe

IRCT registration information

IRCT registration number: **IRCT20190904044697N1**

Registration date: **2019-10-01, 1398/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-01, 1398/07/09**

Update count: **0**

Registration date

2019-10-01, 1398/07/09

Registrant information

Name

Mohammad Abdollahad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-25, 1397/06/03

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Real-time intra-operative in-vivo diagnosis of internal margins involved to breast pre-invasive/invasive cancer cells through pathological classification using a handheld electrochemical system

Public title
Intra-operative real-time diagnostic probe for suspicious lesions using electrochemical tracing of hypoxia glycolysis

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with obvious breast tumor mass, previously diagnosed with solid mass (DCIS, ILC, IDC...). Neo-adjuvant cases with or without a wire guide.
Exclusion criteria:
 No exclusion regarding patients recruitment

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **200**
 More than 1 sample in each individual
 Number of samples in each individual: **6**
 There are 6 distinguished margins in both tumor side (external margin) and body side (internal margin) included: superior, inferior, medial, lateral, superficial and deep. For each patient at least these margins should be tested.

Randomization (investigator's opinion)
Randomized

Randomization description
 We should select almost 200 patients from all categories of breast cancer for in-vivo tests. Among all types of breast cancers, patients with IDC tumors are more than other types (such as phylloids and lobular carcinomas). Our surgical collaborators randomly select and introduce the patients for this trial. Each patient who accepts to take part in the investigation will sign ethical consent. The number of patients needed for this project was determined by the ethics committee. However, we took permission to investigate more patients to ensure the reliability and repeatability of our results.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment

Single

Other design features
 The system lively determines the H2O2 released from cancer or atypical cells, through reverse Warburg effect and hypoxia assisted glycolysis pathways, in a quantitative electrochemical manner. We proposed a matched clinical diagnostic categorization between the pathological results of the tested tissues and response peaks of CDP based on ductal intraepithelial neoplasia (DIN) classification (with the latest reported modifications) based on our primary outcome results. Unique ability in the non-invasive and real-time diagnosis of internal margins with pathological values (from high-risk benign to pre-invasive and invasive cancer lesions) makes CDP a distinct intra-operative tool with simple and small handheld equipment to increase the prognostic factor of the cancer patients.

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

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Approval date

2018-08-18, 1397/05/27

Ethics committee reference number

IR.TUMS.VCR.REC.1397.355

Health conditions studied

1

Description of health condition studied

Breast cancer surgery

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast, Breast cancer surgery, Hyperplasia

Primary outcomes

1

Description

Pathological classification of different breast lesions

correlated with current peaks of CDP. Results show meaningful consistency between DIN (Ductal Intraepithelial Neoplasia) based pathological diagnosis and CDP scoring.

Timepoint

Results will be compared with permanent pathology about 2 weeks after intervention

Method of measurement

Electrochemical Cyclic voltammetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After tumor dissection, all the regions in body side margins named internal margins are tested by CDP. Depend on the size of the tumor and its proximity to one of the margins (not all the margins), some margins must undergo further analysis. The internal regions with more joint boundaries with the tumors would require further scans because of their larger formed internal margins. The head probe needles are single-used and the entered length of the needles into the breast margins are 4 millimeters. Scan region is 3*3*4 mm³ and if CDP score is positive, this area will be dissected for pathological examination.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor afshar hospital

Full name of responsible person

Dr Mohammad Abdolabad

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Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

Motamed cancer institute, Breast cancer research center

Full name of responsible person

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Name of recruitment center

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5

Recruitment center

Name of recruitment center

Bozorgmehr Limited Surgery Center (Di clinic)

Full name of responsible person

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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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Web page address

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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

Breast cancer surgery

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Other areas of specialty/work

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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

Not applicable

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

Starting 6 months after publication.

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.

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

We will send the data to the applicant in 2 weeks.

Comments