

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

In-vivo intra-operative detection of breast margins involved in cancer using hypoxia glycolysis metabolism as neoplastic signaling. A frozen guided clinical trial

Protocol summary

Study aim

Checking the surgical margins in breast cancer patients is a critical step to be ensured from the safe removal of high-risk suspicious cells with minimal dissection of healthy 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.

Design

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

Settings and conduct

When frozen declares some tumor margins as involved external margins, through standard guidelines, cavity side margins must be re-excised and resend for frozen up to be reported as free margins. The surgeon will then use CDP to check all the inner margins and inform the pathologist about the positively scored ones. Then, the pathologist further evaluates the last reciprocal external margins of that internal margins by slide preparation from much more points on that margin. If the pathologist found any suspicious lesions in re-evaluation, he/she informs the surgeon to remove the positively scored margin, otherwise, the surgeon wouldn't remove the CDP positive internal margins, and we record the data of CDP responses.

Participants/Inclusion and exclusion criteria

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

Intervention groups

The surgeon follows the standard guidelines based on frozen pathology. Then CDP will be applied just as a complementary diagnostic tool to check the internal margins after completing the surgery (after checking and removing the involved margins through frozen results of

external margins).

Main outcome variables

As a result, without any CDP induced intervention, the impact of CDP in preventing re-surgery would be evaluated.

General information

Reason for update

Acronym

CDP, Cancer Diagnostic Probe

IRCT registration information

IRCT registration number: **IRCT20190904044697N3**

Registration date: **2020-02-23, 1398/12/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-23, 1398/12/04**

Update count: **0**

Registration date

2020-02-23, 1398/12/04

Registrant information

Name

Mohammad Abdolabad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In-vivo intra-operative detection of breast margins involved in cancer using hypoxia glycolysis metabolism as neoplastic signaling. A frozen guided clinical trial

Public title
Intra-operative real-time diagnostic system for suspicious breast tissue using electrochemical signaling as a complementary method for frozen section pathology

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with noticeable breast tumor mass or previously diagnosed with solid mass (DCIS, ILC, IDC...).

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: 26

Randomization (investigator's opinion)
Randomized

Randomization description
Twenty-six patients need to be recruited 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. 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.

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 the results of CDP. This categorization is 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 small and straightforward 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, Enghelab Ave.

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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

Primary outcomes

1

Description

The pathological classification of different breast lesions correlates 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 3 days after the intervention.

Method of measurement

Electrochemical Cyclic voltammetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The surgeon follows the standard guidelines based on frozen pathology, and will apply CDP as a complementary diagnostic tool to check the inner margins after completing the surgery (after checking and removing the involved margins through frozen results of external margins). Hence, when the margins are declared free after one or further sequences of frozen evaluation, the surgeon will use CDP on all internal margins. Frozen may report some tumor margins as involved external margins, which through standard guidelines, cavity side margins must be re-excised and resend for frozen up to be declared as free external margins by pathologists. In this clinical trial, the surgeon checks the internal lesions by CDP and inform the pathologist about the positively scored ones. Then, the pathologist further evaluates all over the last reciprocal external margin of that inner one by slide preparation from much more points on that margin. If the pathologist found any suspicious lesions in re-evaluation, he/she informs the surgeon to remove the positively scored margin. Otherwise, the surgeon wouldn't remove the CDP's positive reported margins, and we record the data of CDP responses. In the next step, the pathologist will recheck all of the last reciprocal external margins by permanent H&E. Hence, the patient will be recalled to undergone second surgery if any external margins have been missed by frozen and detected in permanent pathology either CDP has detected them or not.

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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Sadeghin Alley (17th West), Khodaverdi St,
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2

Recruitment center

Name of recruitment center

Khatam Ol Anbia hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

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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

Dr Mohammad Hosein Bahreini

Street address

No. 38, West Nastaran Ave (Arab), Khorramshahr St.,
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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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Abdolabad

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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Position

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

Breast cancer surgery

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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

80% of the information about the primary outcome after

de-identifying the participants, can be shared.

When the data will become available and for how long

Starting six 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 one week.

Comments