

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Comparison of the correctness of the excised lesions (with pathology and sonography) in patients with a non-palpable benign breast lesion under the guidance of us-guided skin-marking and lesion local coordinates or guide-wire insertion

#### Protocol summary

##### Study aim

Comparison of excision of non-palpable benign breast lesions under the guidance of US-guided (ultra sound guided) skin-marking and lesion local coordinates or guide-wire insertion from the view of surgery time, specimen weight, and the convenience of the surgeon and radiologist

##### Design

A pragmatic, two arms parallel group non-blind randomized clinical trial

##### Settings and conduct

This study will be conducted as a randomized clinical trial. Participants include women who are candidate for non-palpable benign breast lesion excision. After the simple randomization with sealed envelope, lesion excision in the intervention group will be performed under the guide of us-guided skin-marking and in control group, the lesion will be excised using guide-wire insertion as a routine protocol. The correctness of the excised tumor, time of surgery, the weight of the excised specimen, and the convenience of the surgeon and radiologist will be compared between two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: women with non-palpable benign breast lesions; candidate for lesion excision. Non-inclusion criteria: women who had malignant breast lesions.

##### Intervention groups

Intervention group: Excision of the lesion will be performed under the guidance of us-guided skin-marking. Control group: Lesion excision will be performed using guide-wire insertion (routine protocol).

##### Main outcome variables

Surgery time; Specimen weight; The convenience of surgeon and radiologist.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100706004329N8**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **prospective**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

##### Registration date

2019-04-06, 1398/01/17

##### Registrant information

##### Name

Sadaf Alipour

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

00982177888751 - 00982177883195

##### Email address

salipour@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-09, 1398/01/20

##### Expected recruitment end date

2020-06-09, 1399/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the correctness of the excised lesions (with pathology and sonography) in patients with a non-palpable benign breast lesion under the guidance of us-guided skin-marking and lesion local coordinates or guide-wire insertion

**Public title**

Surgery of non-palpable benign lesion with skin-marking

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria****Inclusion criteria:**

Benign breast lesion Non-palpable lesion

**Exclusion criteria:**

Malignancy in the breast

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization with individual unit and sealed envelopes tool

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

6th floor of Vice chancellor for Research, Central Building of University, Ghods Ave., Keshvarz Blvd.,

**City**

Tehran

**Province**

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**Postal code**

1417653761

**Approval date**

2019-02-02, 1397/11/13

**Ethics committee reference number**

IR.TUMS.VCR.REC.1397.874

**Health conditions studied****1****Description of health condition studied**

Benign breast lesions

**ICD-10 code**

N64.9

**ICD-10 code description**

Disorder of breast, unspecified

**Primary outcomes****1****Description**

The correctness of the excised lesion

**Timepoint**

After surgery

**Method of measurement**

With pathology and sonography

**Secondary outcomes****1****Description**

Time of surgery

**Timepoint**

During surgery

**Method of measurement**

Measuring time with clock in minutes

**2****Description**

Weight of excised specimen

**Timepoint**

After surgery

**Method of measurement**

Measuring weight with digital weighting device in grams

**3****Description**

The convenience of Surgeon

**Timepoint**

After surgery

**Method of measurement**

Questionnaire (Likert scale)

**4****Description**

The convenience of radiologist

**Timepoint**

After radiology

**Method of measurement**

Questionnaire (Likert scale)

**Intervention groups****1****Description**

Intervention group: Skin-marking of benign breast lesions with a pen under the guidance of ultrasonography

**Category**

Treatment - Surgery

**2****Description**

Control group: Marking the lesion with guide-wire insertion (routine protocol)

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Arash women's hospital

**Full name of responsible person**

Sadaf Alipour

**Street address**

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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**Email**

salipour@sina.tums.ac.ir

**Web page address**

<http://arash.tums.ac.ir/>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Ali Sahraian

**Street 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**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**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**

Sadaf Alipour

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for scientific inquiries

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available