

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Relationship between Aspirin use and reduction of breast cancer recurrence rate in patients referred to Breast Cancer Prevention Clinic, 1390

Protocol summary

Summary

Purpose: Determination of relationship between Aspirin use and reduction of breast cancer recurrence rate in patients referred to Breast Cancer Prevention Clinic, 1390 Design study: Randomized, not blinded, not used placebo, single-center, phase 2 or 3 clinical trial Methods: Considering the $\alpha=0.5$ & $\beta=0.8$ and ten percent expect to reduce recurrence of breast cancer in the intervention group and also patients under consideration for two years, the sample size is 400 (200 in each group). Breast cancer patients in Stage 1, 2 and 3 who surgical and adjuvant treatments have been completed and referred to Breast Cancer Prevention Clinic are randomly divided into two groups and is given a 80-mg Aspirin tablets for one group daily and is not given any placebo to other group. Patients who experience gastrointestinal problems and are sensitive to Aspirin are excluded. Patients are followed for two years and are checked in terms of local recurrence & metastasis and patients with each stage are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202218215N1**

Registration date: **2012-02-21, 1390/12/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-02-21, 1390/12/02

Registrant information

Name

Sedigheh Tahmasebi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1234 9334

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tahmasebis@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Relationship between Aspirin use and reduction of breast cancer recurrence rate in patients referred to Breast Cancer Prevention Clinic, 1390

Public title

The effect of Aspirin on breast cancer recurrence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Breast cancer patients in stage 1, 2 and 3 and surgical and adjuvant treatments have been completed; Exclusion criteria: Patients who experience gastrointestinal problems and are sensitive to Aspirin are

excluded.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

no

Secondary trial Id

no

Registration date

empty

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Karim Khan Zand street, Shiraz

City

Shiraz

Postal code

1978-71345

Approval date

2011-11-24, 1390/09/03

Ethics committee reference number

CT-90-5822

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

Breast cancer

ICD-10 code

C50.0 , C5

ICD-10 code description

Nipple and areola, Central portion of breast, Upper-inner quadrant of breast, Lower-inner quadrant of breast, Upper-outer quadrant of breast, Lower-outer quadrant of breast, Axillary tail of breast, Overlapping lesion of breast, Breast, unspecified

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

Clinical examination

Timepoint

2 years

Method of measurement

Clinical examination

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

Mammography

Timepoint

2 years

Method of measurement

Mammography

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

Interventional groups: 200 patients with breast cancer in stage 1 , 2 and 3 is finished surgery and adjuvant therapy, randomly selected and a Aspirin 80 mg is administered daily. Patients are followed two years, and are checked in terms of local recurrence & metastasis and patients with each stage are compared.

Category

Treatment - Drugs

2**Description**

Control group: 200 patients with breast cancer in stage 1 , 2 and 3 is finished surgery and adjuvant therapy, randomly selected and is not given any placebo. Patients are followed two years, and are checked in terms of local recurrence & metastasis and patients with each stage are compared.

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center

Breast Clinic of Motahari
Full name of responsible person
Sedigheh Tahmasebi
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Person responsible for scientific inquiries

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Mohammad Hossein Dabbagh Manesh
Street address
Karim Khan Zand street, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
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General surgeon, Assistant Professor of Shiraz University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty