

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Compare the complementary effect of radiofrequency ablation technique besides chemotherapy in patients with metastatic liver tumors from breast and control group under chemotherapy

Protocol summary

Summary

The purpose of this study is to evaluate the effect of radio frequency ablation (RFA) technique on treatment of liver metastatic tumors from breast cancer. In this randomised clinical trial, patients with liver metastases from breast cancer who refer to interventional radiology centre will be enrolled. Patients should have less than 5 lesions which are smaller than 5 cm. They will be divided into two groups. Patients in the case group take chemotherapy and RFA during their treatment procedure, but in the control group only chemotherapy will be taken. Patients in both groups will be matched based on age, sex, race, tumour type, number of tumours, duration of disease and type of previous treatment (surgery/chemotherapy). CT scan with and without contrast will be done 3 weeks after general chemotherapy in the control group and RFA and chemotherapy in the case group. To assess the treatment response, CT exam will be done for the following 3 and 6 months. The size, frequency, contrast agent absorption and the status of residual liver tumour will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010931062N2**
Registration date: **2017-04-24, 1396/02/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-24, 1396/02/04

Registrant information

Name

zahra mardanshahi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research department, Mazandaran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the complementary effect of radiofrequency ablation technique besides chemotherapy in patients with metastatic liver tumors from breast and control group under chemotherapy

Public title

Compare the complementary effect of radiofrequency ablation technique besides chemotherapy in patients with metastatic liver tumors from breast and control group under chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: liver metastatic lesion from breast tissue verified by pathology; liver metastatic lesion far from intrahepatic bile ducts; liver metastatic lesion far from great veins more than 3 cm
 Exclusion criteria: Acute febrile infection; Cr>2; Ascites; hepatic encephalopathy; INR>1.5; Bill>3; verified extrahepatic metastases; surgery candidates

Age
 From **35 years** old to **65 years** old

Gender
 Female

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **52**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Mazandaran University of Medical Sciences

Street address

Research department of Mazandaran University of Medical Sciences, Moallem square

City

Sari

Postal code

Approval date

2016-04-21, 1395/02/02

Ethics committee reference number

IR.MAZUMS.REC.95.2165

Health conditions studied

1

Description of health condition studied

liver metastases from breast cancer

ICD-10 code

C79.8

ICD-10 code description

Secondary malignant neoplasm of other specified sites

Primary outcomes

1

Description

The status of residual liver tumour

Timepoint

3 weeks after treatment, 3 months and 6 months after treatment

Method of measurement

Evaluate CT scan images with and without contrast

2

Description

Liver tumor size

Timepoint

3 weeks after treatment, 3 months and 6 months after treatment

Method of measurement

Evaluate CT scan images with and without contrast

3

Description

Frequency of liver tumors

Timepoint

3 weeks after treatment, 3 months and 6 months after treatment

Method of measurement

Evaluate CT scan images with and without contrast

4

Description

Contrast agent absorption by liver tumor

Timepoint

3 weeks after treatment, 3 months and 6 months after treatment

Method of measurement

Evaluate CT scan images with and without contrast

Secondary outcomes

empty

Intervention groups

1

Description

Case group will receive both RFA and chemotherapy
 Chemotherapy regimen FEC: Cycle length: 21 days -
 Duration of therapy: 6 to 8 cycles. Fluorouracil 500 mg/m² IV - Once a day Epirubicin 100 mg/ m² IV - Once a day Cyclophosphamide 500 mg/ m² IV - Once a day ----
 ----- RFA is done by Active Tip electrode (Mygene-Korea) and with 1.5, 2 and 3 centimeter ablation depth

Category

Treatment - Other

2

Description

Control group will receive just chemotherapy
Chemotherapy regimen FEC: Cycle length: 21 days -
Duration of therapy: 6 to 8 cycles. Fluorouracil 500
mg/m2 IV - Once a day Epirubicin 100 mg/ m2 IV - Once
a day Cyclophosphamide 500 mg/ m2 IV - Once a day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Partomazand Imaging Center

Full name of responsible person

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research department, Mazandaran University of
Medical Sciences

Full name of responsible person

Mohammad Bagher Montazeri

Street address

Research department of Mazandaran University of
Medical Sciences, Moallem square

City

Sari

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Research department, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Zahra Mardanshahi

Position

Assistant professor/ Radiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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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