Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of efficacy and safety of Diphereline 11.25 mg, Microreline 11.25 mg, and Microreline 3.75mg in premenopausal breast cancer patients

Protocol summary

Study aim

Comparison of efficacy and safety of Diphereline 11.25 mg, Microrelin 11.25 mg, and 3.75mg in premenopausal breast cancer patients.

Design

A three-arm parallel randomized clinical trial without a control group, single-blind, fourth phase on 210 patients, randomization will be done by the random block method and MS EXCEL.

Settings and conduct

This study will be performed at the Breast Cancer Research Center. Before starting systemic therapy, the serum estradiol levels in the three groups will be measured. Then, serum estradiol levels will be measured at the end of the third month in quarterly drug groups and the end of all three injections for monthly drug, and it will be compared in three groups. All patients will be clinically evaluated during treatment in terms of menopause, the interval between menstruation and injection, spotting, and the ability to menopause (menopause and serum estradiol level below 5-10 µ g/ml), then will be compared in three groups. This process will be continued in the sixth, ninth and twelfth months (at the end of the first year) of medicine use (5 times in total). Menopausal symptoms, including hot flashes, vaginal dryness, and the number of hot flashes per day, shivering, and dyspareunia symptoms will be asked and recorded in a table every three months, respectively. At the end of the study, the ability to induce menopause in the two groups with the above factors will be compared.

Participants/Inclusion and exclusion criteria

Age over 18 years Positive estrogen and progesterone receptor Premenopausal patients Perimenopausal patients, If the estradiol levels are similar to premenopausal women.

Intervention groups

Quarterly Diphereline group Quarterly Microreline group Monthly Microreline group

Main outcome variables

Changes in estradiol levels over one year.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201227049847N1**
Registration date: **2021-01-09, 1399/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-09, 1399/10/20**
Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Shahpar Haghighat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8867 9402

Email address

sha_haghighat@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2021-04-04, 1400/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of Diphereline 11.25 mg, Microreline 11.25 mg, and Microreline 3.75mg in premenopausal breast cancer patients

Public title

Efficacy and safety of Diphereline and Microreline 3.75mg in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Positive estrogen and progesterone receptor Premenopausal patients Perimenopausal patients, if they have the same estradiol levels as premenopausal women.

Exclusion criteria:

Existence of metastasis History of hysterectomy and oophorectomy

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

After enrolling subjects in the study, they will assign one of the three study groups using the random six-block method. Before the intervention, a statistician prepared 35 sets of BBCAAC, BCAACB, CCAABB, etc., modes using MS Excel. The letters A, B, and C will be each symbol of one of the study groups by using the draw. Each code of six will be enclosed in a sealed envelope that cannot be read from the envelope. When the patients are visited, one of the envelopes will be randomly selected, and on the order of the letters mentioned in it, the patients will be assigned to one of the study arms.

Blinding (investigator's opinion)

Single blinded

Blinding description

Since the randomization will be done by the relevant person in charge of the clinic, and the recording of the tests and complications will be done by a follow-up physician, in quarterly drug injection groups, the subjects, the observer (oncologist and nurse), and the analyzer will not know the type of drug. In the one-month injection group, it will not be possible to blind the subject and the observer.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Motamed Cancer Institute- Academic Center for Education, Culture and Research

Street address

No.146, South Gandi Ave, Vanak Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1517964311

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.ACECR.IBCRC.REC.1397.003

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Changes in Estradiol level over one year

Timepoint

Before the intervention, 3, 6 and 12 months after the intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Menopausal symptoms

Timepoint

Before the intervention, three, six, nine and twelve months after the intervention

Method of measurement

Menopause Rating Scale

2

Description

Drug side effects

Timepoint

Before the intervention, three, six, nine and twelve months after the intervention

Method of measurement

Drug side effects checklist

Intervention groups

1

Description

The first intervention group: Diphereline 11.25 mg, manufactured by Ipsen France, will be given to patients every three months for one year.

Category

Treatment - Drugs

2

Description

The second intervention group: Microreline 11.25 mg, manufactured by Homa Pharmed Iran, will be given to patients every three months for one year.

Category

Treatment - Drugs

3

Description

The third intervention group: Microreline 3.75 mg, manufactured by Homa Pharmed Iran, will be given to patients monthly for one year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motamed Cancer Institute, Breast Cancer Research Center

Full name of responsible person

Maryam Ansari

Street address

No.146, South Gandi Ave, Vanak Sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Homa Pharmed Company

Full name of responsible person

Morteza Kheirabadi

Street address

No.26 . Nader Alley . Parvin St . West Fatemi St . Tehran

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1418635643

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+98 21 6276 9000

Email

info@homapharmed.com

Web page address

https://www.homapharmed.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Homa Pharmed Company

Proportion provided by this source

100

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Safa Najjar Najafi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Not applicable