

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the preservation of ovarian reserve by endocrine suppression in women undergoing chemotherapy at reproductive ages by (GNRH) gonadotrophin hormone releasing agonists.

Protocol summary

Study aim

Determination the effect of GNRH on preservation ovarian function patients undergoing combination chemotherapy

Design

A total of 60 cancer patients with reproductive age will be studied. All patient's demographic information will be recorded. Patients are randomly allocated into intervention and control groups. In the intervention group, GNRH is started at least 2 weeks before treatment and every 28 days during treatment. In the control group chemotherapy alone is used. Patients include non-Hodgkin's lymphoma, breast cancer, acute lymphoid leukemia.

Settings and conduct

Before starting the treatment, all patients received a detailed history and complete clinical examination and recorded in the clinical records of the patient. Menstruation is also recorded in the case. After treatment, patients will be evaluated for menstruation, and LH, FSH and serum estradiol tests. Ovarian function was evaluated immediately after treatment and 6 months later. The data will be analyzed statistically.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with cancer who require chemotherapy; age greater than 13 and less 50 years old; good performance; absence of a history of chemotherapy; signature of informed consent form; dissatisfaction with oocyte fusion. Exclusion criteria: pregnancy / lactation; incidence of drug complications; history of thromboembolic events; history of osteoporotic fractures; lack of cooperation.

Intervention groups

intervention group: Analogue GNRH with chemotherapy.
Control group: chemotherapy without GNRH.

Main outcome variables

Maintain ovarian function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042091N2**

Registration date: **2019-06-03, 1398/03/13**

Registration timing: **prospective**

Last update: **2019-06-03, 1398/03/13**

Update count: **0**

Registration date

2019-06-03, 1398/03/13

Registrant information

Name

Zahra Mozaheb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3833 2711

Email address

mozahebz@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the preservation of ovarian reserve by endocrine suppression in women undergoing chemotherapy at reproductive ages by (GNRH) gonadotrophin hormone releasing agonists.

Public title

Preserving fertility after chemotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women with cancer who require chemotherapy Age of more than 13 and less than 50 years old Good performance (ECOG: 0-1 No history of previous chemotherapy Sign a Consent Form Dissatisfaction with oocyte fusion

Exclusion criteria:

Pregnancy / Breastfeeding 2. 3. 4. 6. Hypersensitivity reaction or significant side effect of the drug History of thromboembolic events in the patient The history of osteoporotic fractures Patient does not cooperate in the correct treatment process in accordance with the recommended guidelines

Age

From **13 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a randomized list of patients prepared by software, they are divided into two groups by simple randomization.

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 Mashhad University of Medical Sciences

Street address

Daneshgah st, ghorashi building, Research and Technology Deputy

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-05-09, 1398/02/19

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.037

Health conditions studied

1

Description of health condition studied

Preserving fertility following chemotherapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of the effect of GNRH on preservation of fertility and ovarian function in patients undergoing combined chemotherapy

Timepoint

Check immediately and 6 months after chemotherapy

Method of measurement

Perform ovary function assessment tests

2

Description

Menstrual recovery

Timepoint

6 months after treatment

Method of measurement

Question from the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The GNRH intervention group is prescribed at least 2 weeks before starting treatment and every 28 days during treatment with a chemotherapy regimen.

Category

Rehabilitation

2

Description

Control group: Control group: In this group chemotherapy is given without prescribing GNRH or placebo. The patient receives chemotherapy alone.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam-Raza hospital

Full name of responsible person

Zahra Mozaheb

Street address

Imam Reza hospital, Imam Reza square, Ebnesina St,

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi phd

Street address

Deputy of Research and Technology of the Mashhad University of Medical Science, opposite University of Ave. 18, Daneshgah Street

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Grant name

Grant code / Reference number

Mashhad University of Medical Sciences

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Mozaheb

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical oncology

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Hematology- Oncology department, Imam Reza hospital, Imam reza square,

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

General information of patients and the main outcome
and analyzed data

When the data will become available and for how long

After completing sample size

To whom data/document is available

People working at university centers

Under which criteria data/document could be used

In the case of access, they do not have any analysis and
interpretation before the article is published

From where data/document is obtainable

Email: mozahebz@mums.ac.ir

What processes are involved for a request to access data/document

After requesting and reasoning, the need for this
information and how to use this information are available
within 1 week, if available.

Comments