Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 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 / Breastfeeding2. 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 commitee 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
Menstural 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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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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Phone
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Email
vcresearch@mums.ac.ir
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
Street address
Hematology- Oncology department,Imam Reza hospital، Imam reza square,
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Person responsible for updating data

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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