Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the response rate and adverse effect between two groups of adjuvant short course high dose rate intravaginal brachytherapy vs conventional brachytherapy in primary endometrial cancer

Protocol summary

Study aim

1. To compare the response rate between two groups of adjuvant short course high dose rate intravaginal brachytherapy vs conventional brachytherapy in primary endometrial cancer 2. To compare the adverse effect between two groups of adjuvant short course high dose rate intravaginal brachytherapy vs conventional brachytherapy in primary endometrial cancer

Design

In this double arms-randomized phase II trial, 104 endometrial adenocarcinoma patients who meet the inclusion criteria will be recruited. All of the patients had been underwent total abdominal hysterectomy and bilateral salpyngo-oophorectomy (TAH-BSO). They will be entered in one of the treatment groups including intervention including high dose rate short course intravaginal brachytherapy receiving 5 G for 5 days vs. control group consist of conventional brachytherapy of 7 G weekly for 3 fractions. Treatment result and adverse effects will be explained for the patients and Informed consent will be obtained.

Settings and conduct

Patients who referred to radiation oncology ward of Imam Khomeini cancer institute and Mohebbe Yas hospital during year 2017 will be entered in one of two treatment groups.

Participants/Inclusion and exclusion criteria

Patients with stage 1 or 2 of endometrial adenocarcinoma who have been underwent TAH-BSO and referred to radiation oncology ward of Imam Khomeini cancer institute and Mohebbe Yas hospital and also dose not have any comorbidities and dose not need for other adjuvant therapies.

Intervention groups

The intervention group consists of high dose rate short course intravaginal brachytherapy receiving 5 G for 5 days vs. conventional brachytherapy of 7 G weekly for 3 fractions.

Main outcome variables

Response rate; Adverse effect

General information

Reason for update

Acronym

not indicated

IRCT registration information

IRCT registration number: **IRCT20161123031040N4**
Registration date: **2018-01-24, 1396/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-24, 1396/11/04**
Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

Name

farnaz amouzgar hashemi

Name of organization / entity

cancer institute

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2518

Email address

amoozfar@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the response rate and adverse effect between two groups of adjuvant short course high dose rate intravaginal brachytherapy vs conventional brachytherapy in primary endometrial cancer

Public title

A comparison between adjuvant short course high dose rate intravaginal brachytherapy vs conventional brachytherapy in primary endometrial cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who suffer from endometrial adenocarcinoma stage 1 or 2 Patient's age will be between 18 to 75 years Patients who have underwent total abdominal hysterectomy and bilateral sapping-oophorectomy Karnofski Performance Status should be more than 70

Exclusion criteria:

Patient receive other adjuvant therapies like chemotherapy. Histological pathology of papillary serous carcinoma or clear cell carcinoma Presence of commodities like severe hypertension or myocardial infarction Patient refuses the treatment

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Not 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 of Tehran University of Medical Sciences

Street address

No 21, Dameshgh St. , Vali - e Asr Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1498789534589

Approval date

2016-07-16, 1395/04/26

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.304

Health conditions studied

1

Description of health condition studied

Endometrial adenocarcinoma

ICD-10 code

C54.1

ICD-10 code description

Malignant neoplasm of endometrium

Primary outcomes

1

Description

Rectal complication

Timepoint

Evaluation of rectal complications 4, 8 and 12 months after vaginal cuff brachytherapy

Method of measurement

History, physical examination and proctosigmoidoscopy if indicated

2

Description

Urinary complications

Timepoint

Evaluation of urinary complications 4, 8 and 12 months after vaginal cuff brachytherapy

Method of measurement

History, physical examination and urine analysis if indicated

3

Description

Vaginal complications

Timepoint

Evaluation of vaginal complications 4, 8 and 12 months

after vaginal cuff brachytherapy

Method of measurement

History and physical examination

Secondary outcomes

1

Description

Response rate

Timepoint

Assessment of tumor size at the beginning and 4, 8 and 12 months after vaginal cuff brachytherapy

Method of measurement

Assessment of tumor size through vaginal exam

2

Description

Pelvic recurrence

Timepoint

Assessment of pelvic recurrence 4, 8 and 12 months after vaginal cuff brachytherapy

Method of measurement

History and physical exam

3

Description

Vaginal recurrence

Timepoint

Assessment of vaginal recurrence 4, 8 and 12 months after vaginal cuff brachytherapy

Method of measurement

History and physical exam

Intervention groups

1

Description

High dose rate intravaginal brachytherapy with cylinder with total dose of 25 Gray in 5 continuous days during one week after surgery

Category

Treatment - Other

2

Description

Control group: High dose rate intravaginal brachytherapy with cylinder with total dose of 21 Gray in 3 continuous weeks during one week after surgery

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiation Oncology Department of Imam khomeini Cancer Institute and Moheb e Yas Hospital

Full name of responsible person

Afsane Maddah Safaei

Street address

Radiation Oncology Department, Imam khomeini Cancer Institute, Keshavarz Blvd.,Tehran and Moheb e Yas Hospital, Nejattollahi ave,. Tehran

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amoozfar@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Street address

Radiation Oncology Department, Imam khomeini Cancer Institute, Keshavarz Blvd.,Tehran and Moheb e Yas Hospital, Nejattollahi ave,. Tehran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Farnaz Amouzgar hashemi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

Street address
Radiation Oncology Department, Imam khomeini Cancer Institute, Keshavarz Blvd.,Tehran and Moheb e Yas Hospital, Nejattollahi ave,. Tehran

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Data of other research maybe becomes at risk

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The report of study will be released.

When the data will become available and for how long
It will be after publishing the paper.

To whom data/document is available
The results will be accessible for all.

Under which criteria data/document could be used
To administer in clinical decision making the result will be accessible.

From where data/document is obtainable
To receive the results contact to correspondent.

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

To receive the results contact to correspondent.

Comments