

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluating the effect of bowel preparation plus oral Rifaximin on Rectum volume and Dosimetric Parameters in intravaginal High-Dose-Rate Brachytherapy for endometrial and cervical Cancer

Protocol summary

Study aim

1.rectal volume evaluation without rifaximin 2.rectal volume evaluation with rifaximin 3.rectal dosimetric parameters evaluation without rifaximin 4.rectal dosimetric parameters evaluation with rifaximin 5.effect of rifaximin on rectal dosimetric parameters 6.effect of rifaximin on rectal volume 7.effect of rectal volume on rectal dosimetric parameters with rifaximin 8.effect of rectal volume on rectal dosimetric parameters without rifaximin

Design

Two arm parallel group randomised trial without blinding postoperative treatment and outcome assessment

Settings and conduct

24 patient who were referred to brachytherapy ward of Golestan hospital for high dose rate brachytherapy , assessed in 2 sessions . first session with bowel preparation without rifaximin and second session with bowel preparation and with rifaximin 400 mg since 7 days before treatment to investigate the relationship between intestinal preparation with oral rifaximin on Rectal volume and dosimetric indices in high-dose intravaginal brachytherapy in cervical and cervical cancers were selected and entered into the study

Participants/Inclusion and exclusion criteria

Entry requirements: pathology based endometrial and cervical cancer, doing surgical treatment before brachytherapy, correct cylinder insertion No entry conditions: no surgery before brachytherapy treatment, weight above 100 kilogram causing not to do MRI

Intervention groups

intervention group: bowel preparation with polyethylenglycol and bisacodyl tablet since 24 hours before treatment and also rifaximin 400 mg BD since 7 days before treatment control group: bowel preparation with polyethylenglycol and bisacodyl tablet since 24 hours before treatment

Main outcome variables

Rectal volume; Rectal dose-volume parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200208046412N1**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **retrospective**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Faezeh Ebrahimian tabrizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3057

Email address

ebrahimian.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-21, 1398/06/30

Expected recruitment end date

2020-03-11, 1398/12/21

Actual recruitment start date

2019-09-21, 1398/06/30

Actual recruitment end date

2020-03-11, 1398/12/21
Trial completion date
2020-03-11, 1398/12/21

Scientific title
Evaluating the effect of bowel preparation plus oral Rifaximin on Rectum volume and Dosimetric Parameters in intravaginal High-Dose-Rate Brachytherapy for endometrial and cervical Cancer

Public title
Evaluating the effect of bowel preparation plus oral Rifaximin in Brachytherapy for endometrial and cervical Cancer

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
pathology based endometrial and cervical cancer doing surgical treatment before brachytherapy correct cylinder insertion
Exclusion criteria:
no surgery before brachytherapy treatment weight above 100 killogram causing not to do MRI

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
cylindric brachytherapy session
Actual sample size reached: **24**
More than 1 sample in each individual
Actual sample size in each individual: **2**
cylindric brachytherapy session

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 Ahvaz University of Medical Sciences
Street address
Radiooncology Ward, Golestan Hospital, Farvardin Blvd., Golestan
City
Ahvaz
Province
Khuzestan
Postal code
613573318
Approval date
2019-12-29, 1398/10/08
Ethics committee reference number
IR.AJUMS.REC.1398.714

Health conditions studied

1

Description of health condition studied
Endometrial cancer

ICD-10 code
C54.1

ICD-10 code description
Malignant neoplasm of endometrium

2

Description of health condition studied
Cervical cancer

ICD-10 code
C53.9

ICD-10 code description
Malignant neoplasm of cervix uteri, unspecified

Primary outcomes

1

Description
Rectal volume

Timepoint
Before(basement) and 7 days after oral Rifaximin

Method of measurement
HDR plus 3.0.8 brachytherapy , treatment planning, Bebig & Ziegler company

2

Description
Rectal Dose-volume parameters

Timepoint
Before(basement) and 7 days after oral Rifaximin

Method of measurement
HDR plus 3.0.8 brachytherapy treatment planning, Bebig & Ziegler company

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: bowel preparation with polyethylenglycol and bisacodyl tablet since 24 hours before treatment and also rifaximin 400 mg BD since 7 days before treatment

Category

Treatment - Drugs

2

Description

Control group: bowel preparation with polyethylenglycol and bisacodyl tablet since 24 hours before treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Sasan Razmjoo

Street address

Radiooncology Ward, Golestan Hospital, Farvardin Blvd., Golestan

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Ahvaz

Province

Khuzestan

Postal code

613573318

Phone

+98 61 3374 3057

Email

ebif1988@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Radiooncology Ward, Golestan Hospital, Farvardin Blvd., Golestan

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ahvaz

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Khuzestan

Postal code

613573318

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Email

ebif1988@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Faezeh Ebrahimian Tabrizi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Radiooncology Ward, Golestan Hospital, Farvardin Blvd., Golestan

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Person responsible for scientific inquiries

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Resident

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Person responsible for updating data**Contact****Name of organization / entity**

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Fax**Email**

ebif1988@gmail.com

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

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

data will be achievable after unidentifying of patients information

When the data will become available and for how long

since 1399

To whom data/document is available

data will be achievable just for scientific institutions

Under which criteria data/document could be used

data will be achievable to be used for patient treatment in the other treatment centers and to report the data.

From where data/document is obtainable

email address: ebif1988@gmail.com, razmjoo-s@ajums.ac.ir, m0bile phone number: +989129412399, address: Radiooncology ward, Golestan hospital, Farvardin Blvd., Golestan, ahvaz, khouzestan

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

with sending request through email address or number or addresses mentioned, and after decision of scientific in charge of research, the data will be sent

Comments