

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

acute and subacute complications of short course brachytherapy compared with conventional brachytherapy treatment in patients with cervical cancer after completion of external radiotherapy

Protocol summary

Study aim

acute and subacute complications including cystitis, proctitis and vaginitis of short course brachytherapy compared with conventional brachytherapy treatment of patients with cervical cancer

Design

The study was a non-randomized clinical trial among 49 patients with cervical cancer in stages one to four.

Settings and conduct

cervical cancer patients who referred to Imam Khomeini hospital were non randomly divided in 2 groups of intervention and control for brachytherapy after external chemoradiation

Participants/Inclusion and exclusion criteria

inclusion criteria: cervical cancer, Age less than 70 years ,Histology of squamous cell carcinoma and adenocarcinoma, Appropriate clinical performance status, clinical disease stage one to four, Hemoglobin higher than or equal to 10; exclusion criteria: Recurrences, Those who have received other treatments such as surgery.

Intervention groups

intervention group: 3 high dose rate brachytherapy sessions by multi source device built by BEBIG company were administered every other day during 1 week to reducing overall treatment time. applicators were including tandem ovoid and tandem cylinder needle depended on response to external radiation. brachytherapy is a kind of radiotherapy that involves placing radioactive material(radium) inside body(cervix). We administrated 85-90Gray to high risk Clinical Target Volume and 70-75Gray to Intermediate Risk clinical target volume. Control group. 3 brachytherapy sessions by multi source device built by BEBIG company were administered 1 session every week during 3 week. administration dose was similar in both groups.

Main outcome variables

cystitis, proctitis ,vaginitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047815N1**

Registration date: **2020-08-22, 1399/06/01**

Registration timing: **retrospective**

Last update: **2020-08-22, 1399/06/01**

Update count: **0**

Registration date

2020-08-22, 1399/06/01

Registrant information

Name

maryam garousi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2288 4548

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

2017-04-09, 1396/01/20

Actual recruitment end date

2019-02-18, 1397/11/29

Trial completion date

2019-04-04, 1398/01/15

Scientific title

acute and subacute complications of short course brachytherapy compared with conventional brachytherapy treatment in patients with cervical cancer after completion of external radiotherapy

Public title

Comparison of treatment outcomes and complications of short-term and long-term brachytherapy in patients with cervical cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age less than 70 years old histopathology Adenocarcinoma & squamous cell carcinoma suitable performance status Stage 1b-4a hemoglobin more than 10 Cervical cancer patients Females

Exclusion criteria:

Recurrent disease other treatment procedure like surgery

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Actual sample size reached: **49**

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

Tehran university of Medical Sciences;Poursina Street,Tehran , Tehran Province,

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.085

Health conditions studied

1

Description of health condition studied

Cervical Cancer

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

the rate of cystitis based on common terminology criteria for adverse events

Timepoint

assess the symptoms before brachytherapy, 0- 30 - 90 days after treatment

Method of measurement

Side effects were recorded by radiation oncologist using the Common terminology criteria for adverse events(CTCAE) guideline.

2

Description

the rate of proctitis based on common terminology criteria for adverse events

Timepoint

assess the symptoms before brachytherapy, 0- 30 - 90 days after treatment

Method of measurement

Side effects were recorded by radiation oncologist using the Common terminology criteria for adverse events(CTCAE) guideline.

3

Description

the rate of vaginitis based on common terminology criteria for adverse events

Timepoint

assess the symptoms before brachytherapy, 0- 30 - 90 days after treatment

Method of measurement

Side effects were recorded by radiation oncologist using the Common terminology criteria for adverse events(CTCAE) guideline.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We performed pelvic MRI for each patient to determine stage of cancer. Then according to three dimensional planing and physics calculation, study participants were treated with external chemoradiation (50 Gy in 25 fractions) with a linear accelerator. They also received weekly Cisplatin for 5 weeks. MRI was done immediately after completion of external chemoradiation . three high dose rate brachytherapy sessions by afterloading multi source device built by BEBIG company were administered every other day during 1 week for reducing overall treatment time. brachytherapy is a procedure that involves placing radioactive material(radium) inside the body(cervix). applicator selection depended on initial tumor and response rate to the external chemoradiation including tandem ovoid, tandem cylinder and tandem cylinder needle. if tandem ovoid did not covered sufficiently we used needle. We administrated dose of 85 to 90Gray to high risk clinical target volume and 70 to 75Gray to intermediate clinical target volume.

Category

Treatment - Other

2

Description

In control group We performed pelvic MRI for each patient to determine stage of cancer. Then according to three dimensional planing and physics calculation, study participants were treated with external chemoradiation (50 Gy in 20 fractions) with a linear accelerator. They also received weekly Cisplatin for 5 weeks. high dose rate brachytherapy by afterloading multi source device built by BEBIG company was given to patients over 3 weeks (1 session in each week). brachytherapy is a procedure that involves placing radioactive material(radium) inside the body(cervix). Applicator selection and insertion dose was selected based on response to external chemoradiation and baseline status of tumor including tandem ovoid, tandem cylinder and tandem cylinder needle. if tandem ovoid did not covered sufficiently we used needle. We administrated dose of 85 to 90Gray to high risk clinical target volume and 70 to 75Gray to intermediate clinical target volume.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Dr Mahdi Aghili

Street address

Imam Khomeini Hospital Complex , end of Keshavarz Boulevard,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

No 206, First Floor, Official Building, Medical Faculty, Poursina Street, 16th Azar Street, Keshavarz Blvd.

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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

Iran University of Medical Sciences

Full name of responsible person

Maryam Garousi

Position

Assistant professor of Radiation oncology

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Department of Radiation oncology ,Iran University of
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Garousi

Position

Assistant Professor of radiation oncology

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

There is no more information

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

No - There is not 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