

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of addition of concurrent Capecitabine to brachytherapy in patients with advanced cervical cancer

Protocol summary

Study aim

Evaluating the effect of capecitabine use during brachytherapy on improving local control and survival in advanced cervical cancer

Design

A phase II, two arm, non- randomized clinical trial, including an intervention and a control group. The intervention group includes 35 patients, recruited during the allotted period, from patients referred for definitive chemoradiotherapy. Comparison is done at the end of one year of follow up, in terms of no of recurrent cases and side effects of intervention with control group, chosen either from previously treated patients, or patients not willing to enter trial, and matched based on stage, comorbidities and response to external chemoradiotherapy.

Settings and conduct

Patient recruitment will happen in three centers, two university hospitals (Omid and Emam Reza hospitals) and a charity hospital (Reza Radiotherapy Oncology Center). All patients will be referred for Brachytherapy to Reza Radiotherapy Oncology Center after the standard external chemoradiotherapy. Patients in the study group are put on concurrent capecitabine at the time of brachytherapy treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria: definite diagnosis of cervical cancer on pathology sample, histology of SCC or adenocarcinoma, stage IB-IVA, adequate performance status Exclusion criteria : patient's reluctance to participate in the trial, uncontrolled comorbidities, eg Diabetes and Hypertension, and Warfarin use.

Intervention groups

Intervention group includes advanced cervical cancer patients who are put on oral capecitabine 825 milligram per meter square body surface area twice daily for 10 to14 days during brachytherapy Control group includes advanced cervical cancer patients who have been treated with standard treatment, that is brachytherapy is

done without chemotherapy

Main outcome variables

adverse effects, overall survival and disease free survival

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210306050600N1**

Registration date: **2021-03-26, 1400/01/06**

Registration timing: **prospective**

Last update: **2021-03-26, 1400/01/06**

Update count: **0**

Registration date

2021-03-26, 1400/01/06

Registrant information

Name

soudeh arastouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3842 6082

Email address

arastoueis971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-30, 1400/01/10

Expected recruitment end date

2022-03-30, 1401/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of addition of concurrent Capecitabine to brachytherapy in patients with advanced cervical cancer

Public title
Brachytherapy with concurrent Capecitabine in advanced cervical cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
definite diagnosis of cervical cancer in the pathological sample histology of SCC or Adenocarcinoma stage IB-IVA based on gynecologic examination and imaging, making these patients chemoradiotherapy candidates no evidence of distant metastasis adequate performance status (ECOG ≥ 2)
Exclusion criteria:
not willing to enter the trial uncontrolled comorbidities, like diabetes mellitus and hypertension warfarin use

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: 35

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
Patient who are recruited into the trial, will be placed in the intervention arm. Control group will be matched patients who have not received concomitant chemotherapy with brachytherapy, either have not entered the trial or those previously treated.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashad University of medical

Sciences
Street address
Daneshgah Avenue
City
Mashad
Province
Razavi Khorasan
Postal code
9176613775
Approval date
2021-02-28, 1399/12/10
Ethics committee reference number
IR.MUMS.MEDICAL. REC.1399. 765

Health conditions studied

1

Description of health condition studied

Cervical cancer, FIGO stage IB-IVA

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

disease free survival

Timepoint

every 3 months after intervention for 12 months

Method of measurement

Using patients' registries, which are the result of patient's follow up visits every three months after completion of treatment to the treating doctor. Recurrence could be proved using biopsy or imaging.

2

Description

Acute Gastrointestinal side effects: nausea and vomiting

Timepoint

During each brachytherapy session. which happens every second or third day

Method of measurement

By history taking, and the severity of this side effect will be recorded based on Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

3

Description

Acute hematologic side effects: Anemia

Timepoint

during every brachytherapy session which is done every second or third day or weekly during intervention

Method of measurement

By history taking, and looking for signs of cytopenias, like bruises, fever, weakness and mucositis. In case of suggesting history, Complete blood count is requested,

otherwise a routine Complete blood count is done weekly

4

Description

Acute hematologic side effects: leucopenia

Timepoint

During every brachytherapy session which is done every second or third day or weekly during intervention

Method of measurement

By history taking, and looking for signs of leukopenia, like fever and mucositis. In case of suggesting history, Complete blood count is requested, otherwise a routine Complete blood count is done weekly

5

Description

Acute gastrointestinal side effects: diarrhoea

Timepoint

During each brachytherapy session, which happens every second or third day

Method of measurement

By history taking, and the severity of this side effect will be recorded based on Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

6

Description

Hand foot syndrome

Timepoint

During each brachytherapy session, which happens every second or third day

Method of measurement

By physical examination, and the severity of this side effect will be recorded based on Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

Secondary outcomes

1

Description

Overall survival(survival from the time of diagnosis till death)

Timepoint

every 3 months after the intervention

Method of measurement

Results of 12 months of follow up of patients regarding overall survival will be recorded using patient's records or in case of lack of adherence to follow up, through phone call

2

Description

Acute hematologic side effect: Thrombocytopenia

Timepoint

Every brachytherapy session, which happens every second or third day

Method of measurement

By history taking, asking for any bleeding or bruises, in

case of positive history a complete blood count is requested. In case of negative history, a complete blood count is routinely done weekly during brachytherapy treatment, which takes ten to fourteen days,

Intervention groups

1

Description

Intervention group: patients who are eligible to enter the trial, are put on Capecitabine 825mg/m² twice daily during their brachytherapy treatment, starting from the first fraction of their brachytherapy treatment till the last fraction, which can take between 10-14 days.

Capecitabine is an oral chemotherapy drug, which can also increase the sensitivity of cells to radiation. In this study, capecitabine-ACTE will be used.

Category

Treatment - Drugs

2

Description

Control group: patients who have received the current standard treatment, that is brachytherapy done without concurrent chemotherapy, are compared with intervention group after they are matched based on variables like stage of disease, comorbidities and performance status. This group can be chosen from the patients who have not entered the trial, or patients who have received the standard treatment in the past.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Soudeh Arastouei

Street address

Omid hospital, Alandasht square, Kooh-Sangi Avenue,

City

Mashad

Province

Razavi Khorasan

Postal code

9176613775

Phone

+98 51 3842 6082

Fax

+98 51 3842 8622

Email

omidhos@mums.ac.ir

Web page address

<https://omid.mums.ac.ir/>

2

Recruitment center

Name of recruitment center

Reza Radiotherapy and oncology center

Full name of responsible person

Fatemeh Homaei Shandiz

Street address

19th Rafsanjani, 7th Azar square, Shahrak Gharb

City

Mashad

Province

Razavi Khorasan

Postal code

9184166759

Phone

+98 51 3500 8715

Email

info@rroc.ir

3

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Soudeh Arastouei

Street address

Emam Reza hospital, Emam reza hospital square,
Ebn-e-Sina Avenue

City

Mashad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

emamreza@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah Avenue

City

Mashad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

Grant name**Grant code / Reference number****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

Soudeh Arastouei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Omid Hospital, Alandasht square, Kooh-Sangi Avenue

City

Mashad

Province

Razavi Khorasan

Postal code

9176613775

Phone

+98 51 3842 6082

Email

arastoueis971@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Homaei Shandiz

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

Street address

Omid hospital, Alandasht square, Kooh-Sangi Avenue

City

Mashad

Province

Razavi Khorasan

Postal code

9176613775

Phone

+98 51 3842 6082

Email

Homaeef@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Soudeh Arastouei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Omid Hospital, Alandasht square, Kooh-Sangi avenue

City

Mashad

Province

Razavi Khorasan

Postal code

9176613775

Phone

0099 51 38426082

Email

arastoueis971@mums.ac.ir

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

De-identified demographic information and data about the primary outcome measures will be shared

When the data will become available and for how long

starting 6 months after the publication

To whom data/document is available

data will only be available to people working in academic institutions

Under which criteria data/document could be used

data will only be available for research oriented purposes

From where data/document is obtainable

In order to access the data, applicant should send an email requesting access, to Dr Soudeh Arastouei(arastoueis971@mums.ac.ir)

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

After receiving the email, communication will be done with the ethic committee of Mashad university of medical sciences for further authorization

Comments