

# 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  $\geq$ 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/m<sup>2</sup> 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

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**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

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9137913316

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**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

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**Province**

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9138813944

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**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

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Omid Hospital, Alandasht square, Kooh-Sangi Avenue

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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

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**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

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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**

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**