Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparative of neoadjuvant chemotherapy fallowed by definitive chemo-radiotherapy and adjuvant chemotherapy versus definitive chemoradiotherapy alone in locally advanced cervical cancer

Protocol summary

Study aim
Determining and comparing the response rate and side effects

Design
Prospective non-randomized clinical trial with 70 patients will be divided into two groups.

Settings and conduct
Patients with advanced cervical cancer in Imam Hossein Hospital will be divided into two groups. In the study group, they will first undergo six courses of chemotherapy, then perfusion MRI evaluation, and in case of clinical response, chemotherapy will continue for up to nine weekly cycles. Patients who did not respond to neoadjuvant chemotherapy will receive six weeks of adjuvant chemotherapy. Patients who have not responded to neoadjuvant chemotherapy will receive immediate standard chemoradiation

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women with advanced cervical cancer (FIGO Ib3-II-III-IVA) ages between 20 to 80 years.
Exclusion criteria: previous treatment with neoadjuvant chemotherapy; history of last surgical treatment; history of radiotherapy in the pelvis and abdomen.

Intervention groups
Evaluation and comparison of two treatment protocols including neoadjuvant and adjuvant chemotherapy with definite chemoradiotherapy compared to definitive chemoradiotherapy alone in patients with advanced cervical cancer

Main outcome variables
Improve response to treatment; improve disease-free survival for one and two years; reduce side effects of radiation therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211011052730N1**
Registration date: **2024-01-02, 1402/10/12**
Registration timing: **prospective**

Last update: **2024-01-02, 1402/10/12**
Update count: **0**

Registration date
2024-01-02, 1402/10/12

Registrant information

Name
robab anbiaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7343 3000

Email address
anbiaee-mm@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-29, 1402/12/10

Expected recruitment end date
2026-03-01, 1404/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative of neoadjuvant chemotherapy fallowed by

definitive chemo-radiotherapy and adjuvant chemotherapy versus definitive chemoradiotherapy alone in locally advanced cervical cancer

Public title
Comparison of chemotherapy before and after definitive chemotherapy-radiotherapy with definitive chemotherapy-radiotherapy alone in patients with advanced cervical cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with advanced cervical cancer (FIGO Ib3-II-III-IVA)
Exclusion criteria:
Previous treatment with neoadjuvant chemotherapy History of previous surgical treatment History of radiotherapy in the pelvis and abdomen
Age
From **20 years** old to **80 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **35**
More than 1 sample in each individual
Number of samples in each individual: **35**
35 patients in the control group who will receive standard definitive chemoradiation treatment and 35 patients in the treatment group who will receive neoadjuvant and adjuvant chemotherapy with definitive chemoradiation
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 Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Shahid Shahriari Square, Evin
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2021-11-14, 1400/08/23
Ethics committee reference number
IR.SBMU.MSP.REC.1400.557

Health conditions studied

1

Description of health condition studied
Cancer of cervix
ICD-10 code
C53.0
ICD-10 code description
Malignant neoplasm of endocervix

Primary outcomes

1

Description
Disease free survival
Timepoint
One year and two year after intervention
Method of measurement
Physical exam and pelvic MRI

2

Description
Improved treatment response
Timepoint
One year and two year after intervention
Method of measurement
Physical exam and pelvic MRI

3

Description
reduction of radiation therapy-related side effects.
Timepoint
One year and two year after intervention
Method of measurement
History and Physical exam and pelvic MRI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One group will undergo a

neoadjuvant protocol along with concomitant chemoradiotherapy. Initially, patients will receive four cycles of weekly carboplatin AUC=2 and paclitaxel 80mg/m2, followed by an evaluation with abdominopelvic diffusion MRI to assess the response rate. Patients showing a favorable response will continue chemotherapy for up to nine weekly cycles. Those who do not respond favorably will immediately commence definitive chemoradiotherapy with cisplatin 40mg/m2 concurrently with 40 to 45Gy EBRT and a 12 to 20Gy boost to the gross node if necessary. Based on indications, they will then receive 30Gy in 3 fractionations over 3 weeks of HDR brachytherapy. Individuals who respond to neoadjuvant chemotherapy will be treated with adjuvant six cycles of weekly carboplatin and paclitaxel. At the conclusion of all treatment stages, all patients will enter the follow-up phase and will be evaluated every three months by gynecologists and radiation oncologists

Category

Treatment - Drugs

2

Description

Control group: The second group will undergo treatment with definitive chemoradiotherapy, including cisplatin 40mg/m2 concurrently with 40 to 45Gy EBRT and a 12 to 20Gy boost to the gross node if necessary. Based on indications, they will receive 30Gy in 3 fractions over 3 weeks of HDR brachytherapy alone. At the end of all treatment stages, patients will enter the follow-up phase and will be evaluated every three months by gynecologists and radiation oncologists

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Robab Anbiaee

Street address

South Madani St.

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1617763141

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anbiaee-mm@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra bakhtiyari

Street address

Shahid Beheshti University of Medical Sciences, Shahid Shahriari Square, Evin

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zahrabakhtiyari545@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahrzad Ebrahimi

Position

Radioncology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

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Position
Associate Professor

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Specialist

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Person responsible for updating data

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Chemotherapy and radiotherapy protocol. Examinations and pathology and patient imaging

When the data will become available and for how long
After printing the results

To whom data/document is available
Researchers in scientific and academic institutions

Under which criteria data/document could be used
Provide an official license from the relevant scientific and academic institution

From where data/document is obtainable
shahrzad.ebrahimi1366@gmail.com

What processes are involved for a request to access data/document
Email to the address mentioned above and after confirmation and confirmation of the validity of the letter of introduction of the documents will be emailed to him/her

Comments