Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

To evaluate Neoadjuvant chemotherapy followed by chemoradiation in patients with unresectable cervical cancer

Protocol summary

Study aim
To evaluate response to treatment of neoadjuvant chemotherapy followed by chemoradiation in patients with unresectable cervical cancer

Design
Phase II clinical trial with single group including 74 subjects who referred and follow up for 3 months after treatment

Settings and conduct
Newly diagnosed unresectable cervical cancer patients who referred to Shiraz radiation oncology department recieved four cycle chemotherapy in form of carboplatin with (Area under curve AUC:5) and paclitaxel(175 per square meter) everey 3 weeks after obtaining informed consent,then chemoradiation with External beam radiotherapy and brachytherapy up to 80-90 Gy to high risk clinical target volume and concurrent chemotherapy with cisplatin (40 mg per square meter) and then response to treatment evaluate three months after treatment by recist1.1 guideline with MRI

Participants/Inclusion and exclusion criteria
Newly diagnised unresectable cervical cancer without history of metastasis and adequate bone marrow,hepatic,renal functionand and age 18 to 75 years and performance status 0 and 1 without Previous pelvic radiation , Serious medical illnessh,hypersensitivity to chemotherapy agent

Intervention groups
single arm group treated by neoadjuvant chemotherapy

Main outcome variables
Response to treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210808052110N1**
Registration date: **2021-10-21, 1400/07/29**
Registration timing: **prospective**

Last update: **2021-10-21, 1400/07/29**
Update count: **0**

Registration date
2021-10-21, 1400/07/29

Registrant information
Name
Marziye Heidarpourfard
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3823 5257
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heidarpourfard@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2022-06-21, 1401/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To evaluate Neoadjuvant chemotherapy followed by chemoradiation in patients with unresectable cervical cancer

Public title
To evaluate Neoadjuvant chemotherapy in treatment of unresectable cervical cancer patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1.Unresectable cervical cancer(IIB toIVA,IB3,IIAmore than 4cm) 2.No history of metastasis 3.Adequate renal function(GFR more than 60ml per min per1.73) 4.Adequate hepatic function(Liver enzyme<5* upper limit normal) 5.Adequate bone marrow function(Absolute neutrophil>1500) 6-Without history of systemic disease 7.Absence of active infection 8.Absence of previous or concurrent oncology pathology 9.ECOG performance status 0 and 1 10.Age 18 to 75 years
Exclusion criteria:
1-Previous pelvic radiation 2-Pregnancy 3-Serious medical illness 4-Hypersensitivity to chemotherapy agent
Age
From **18 years** old to **75 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz university of medicine
Street address
Shiraz university of medicine-in front of Felestin street-Zand street-Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2021-06-21, 1400/03/31
Ethics committee reference number
IR.SUMS.MED.REC.1400.173

Health conditions studied

1

Description of health condition studied
cancer of cervix
ICD-10 code
C53
ICD-10 code description
Malignant neoplasm of cervix uteri

Primary outcomes

1

Description
Response to treatment 3 months after fulfilling it
Timepoint
3 months after fulfilling treatment
Method of measurement
To do MRI and evaluate response to treatment by recist 1.1 guideline

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Recieving 4 course chemotherapy with carboplatin (Area under curve ;AUC:5)and paclitaxel (175mg per square meter)every three week before chemoradiation with External beam radiation and brachytherapy up to 80 to 90Gy to high risk Clinical target volume (CTV)with prescribing concurrent cisplatin weekly(40mg per square meter)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiation oncology department of Shiraz university of medicine
Full name of responsible person
Marzieh Heidarpourfard
Street address
Namazi hospital-Namazi square-Zand street-Shiraz
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+98 71 3647 4326
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Yones Ghasemi
Street address
7th floor-Shiraz university of medical science-Zand street
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7134814336
Phone
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vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Heidarpourfard
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Individual data of study participants and all data can be shared after unrecognized them
When the data will become available and for how long
Access period starts 12 months after the results are published
To whom data/document is available
Researchers of university scientifc institutes
Under which criteria data/document could be used
Any kind of analysis can be done on the delievered data after it is clarified and proved
From where data/document is obtainable
Marzie Heidarpourfard,email adress:heidarpourfard@sums.ac.ir
What processes are involved for a request to access data/document
Please send me an email explaining your request for which part of the data you need and description of the analysisin question. If I see it is fit,the data will be emailed to you within a week
Comments