Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Inquiry into pathologic response, complications, and overall survival in patients with locally advanced cervical cancer treated by neo-adjuvant chemotherapy and surgery

Protocol summary

Summary

1. Objectives: To evaluate the pathologic response, treatment complications, and overall survival in patients with cervical cancer who are treated by neo-adjuvant chemotherapy and surgery. 2. Design: The study is single-grouped, non-blinded, one-centered, and in phase two of clinical trials. 3. Setting and conduct: A total of 30 patients will be selected by convenience sampling method from patients treated in the Radiation Oncology Ward of Imam Reza Hospital in Mashhad. 4. Major inclusion criteria: women aged between 18 and 70 years; definitive pathologic diagnosis of squamous cell carcinoma; and being in stages IB2, IIA2, and IIB according to the International Federation of Gynecology and Obstetrics classification. Main exclusion criteria: history of injection of chemotherapy drug during the four weeks preceding the study; and serious comorbidities such as cardiac disease, poorly controlled diabetes mellitus, malignant hypertension, or bleeding tendency. 5. Intervention: Pretreatment evaluation includes examination, pelvic magnetic resonance imaging, abdominal sonography, and chest x-ray. Patients receive three one-week periods of neo-adjuvant chemotherapy with paclitaxel (135 milligrams per square meter) on day 1 and cisplatin (75 milligrams per square meter) on day 2 every three weeks for three cycles. Patients without desirable response to chemotherapy will undergo standard pelvic chemoradiotherapy. In case the disease worsens in the 4 to 6 weeks later, the patient will undergo Wertham surgery along with three further chemotherapy cycles. The patients will be candidate for postoperative adjuvant radiation in case they have positive surgical margins, lymph nodes or parametric involvement, or at least two of the following factors: deep stromal invasion, lymphovascular invasion, or size greater than 4 centimeters in the histopathology report of the surgical specimen. 6. Main outcome measures: Pathologic response of the tumor to treatment will be assessed at the first presentation, after each cycle, and after surgery. Complication of chemoradiotherapy (e.g., nausea, vomit, neutropenia, edema, and neauropathy) will be evaluated after each cycle. Overall survival will be assessed one year after initiation of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090236033N1**
Registration date: **2017-10-22, 1396/07/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name
Elahe Aghel
Name of organization / entity
Omid Hospital
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2016-12-10, 1395/09/20

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Inquiry into pathologic response, complications, and overall survival in patients with locally advanced cervical cancer treated by neo-adjuvant chemotherapy and surgery

Public title

Pathologic response, side-effects, and overall survival in cervical cancer under treatment with neo-adjuvant chemotherapy and surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Definitive pathologic diagnosis of squamous cell carcinoma; stages IB2, IIA2, and IIB based on the International Federation of Gynecology and Obstetrics classification; age between 18 and 70 years; World Health Organization performance of grade 2 or lower; adequate renal and hepatic function and bone marrow reserve (i.e., absolute granulocyte count equal to or above 2×103 per liter, platelet count equal to or above 100×103 per liter; hemoglobin equal to or above 8.0 grams per deciliter, and glomerular filtration rate equal to or above 50); feasibility of follow-up in the ordered time; and informed consent. Exclusion criteria: history of injection of chemotherapy drug in four weeks before study; serious comorbidities, for example, cardiac disease, poorly controlled diabetes mellitus, malignant hypertension, or bleeding tendency; overt infection; multiple concurrent active cancers; neuropathy grade 2 or greater; pregnancy; and history of serious hypersensitivity or allergy to cisplatin and paclitaxel.

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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 Mashhad University of Medical Sciences

Street address

Vice-chancellery for Reasearch, Mashhad University of Medical Sciences, Daneshgah Ave.,

City

Mashhad

Postal code

Approval date

2016-12-08, 1395/09/18

Ethics committee reference number

IR.MUMS.fm.REC.1395.405

Health conditions studied

1

Description of health condition studied

locally advanced cervical cancer

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

edema

Timepoint

after each course of chemotherapy

Method of measurement

Clinical examination

2

Description

Clinical response of tumor to treatment

Timepoint

At the first presentation, after each cycle of chemotherapy, and after surgery

Method of measurement

Physical examination and pathology

3

Description

Overall survival

Timepoint

On year after initiation of treatment

Method of measurement

Physical examination

4

Description

Nausea

Timepoint

after each course of chemotherapy

Method of measurement

Physical examination

5

Description

Vomit

Timepoint

after each course of chemotherapy

Method of measurement

Physical examination

6

Description

neutropenia

Timepoint

after each course of chemotherapy

Method of measurement

complete blood count

7

Description

Neuropathy

Timepoint

after each course of chemotherapy

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The study has a single group. Pretreatment evaluation includes examination, pelvic magnetic resonance imaging, abdominal sonography, and chest x-ray. Patients receive three one-week periods of neo-adjuvant chemotherapy with paclitaxel (135 milligrams per square meter) on day 1 and cisplatin (75 milligrams per square meter) on day 2 every three weeks for three cycles. Patients without desirable response to chemotherapy will undergo standard pelvic chemoradiotherapy. In case the disease worsens in the 4 to 6 weeks later, the patient will undergo Wertham surgery along with three further chemotherapy cycles. The patients will be candidate for postoperative adjuvant radiation in case they have positive surgical margins, lymph nodes or parametric involvement, or at least two of the following factors: deep stromal invasion, lymphovascular invasion, or size greater than 4 centimeters in the histopathology report of the surgical specimen. Pathologic response of the tumor to treatment will be assessed at the first presentation, after each cycle, and after surgery. Complication of chemoradiotherapy (e.g., nausea, vomit, neutropenia, edema, and neauropathy) will be evaluated after each cycle. Overall survival will be assessed one year after initiation of intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiation Oncology Ward of Imam Reza Hospital

Full name of responsible person

Dr Elahe Aghel

Street address

Radiation Oncology Ward, Imam Reza Hospital, Ibn-Sina Ave.,

City

Mashhad,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery for Research of Mashhad University of Medicla Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Vice-chancellery of Reasearch and Technology, Mashhad University of Medical Sciences, Daneshgah Ave.,

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellery for Research of Mashhad University of Medicla Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Elahe Aghel
Position
Resident of Radiation Oncology
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Person responsible for scientific inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty