

A study to assess the safety and efficacy of chemotherapy and surgery in treatment of cervical cancer

Submission date 11/07/2022	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/07/2022	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/08/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Although radical surgery and radiation therapy were feasible treatment plans for patients with locally advanced cervical cancer (LACC), the optimal treatment plan remained controversial. Neoadjuvant chemotherapy (NACT) followed by radical surgery has been widely used for patients with LACC to reduce tumor volume, improve the rate of resection and control the potential micro-metastasis. However, there has been no study reporting the effect of NACT with carboplatin-paclitaxel plan. Therefore we performed this retrospective study to investigate the clinical effects of NACT regiment carboplatin-paclitaxel.

Who can participate?

Adult females diagnosed with cervical cancer.

What does the study involve?

Retrospectively compare 5-year overall survival, 5-year overall survival and cumulative postoperative radiation rate between LACC patients who received NACT followed by PRS and patients who received PRS.

What are the possible benefits and risks of participating?

Benefits include potential exemption from radiation therapy and improvement of quality of life. There are no risks of participating.

Where is the study run from?

Union Hospital, Tongji Medical College, Huazhong University of Science and Technology (China)

When is the study starting and how long is it expected to run for?

January 2018 to May 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Prof Zehua Wang
zehuawang@hust.edu.cn

Contact information

Type(s)

Principal investigator

Contact name

Prof Zehua Wang

ORCID ID

<https://orcid.org/0000-0001-6423-8219>

Contact details

Jiefang Avenue #1277
Wuhan
China
430022
+86 027 85726993
zehuawang@hust.edu.cn

Additional identifiers

Study information

Scientific Title

Retrospective analysis of neoadjuvant chemotherapy on postoperative treatment in patients with cervical cancer

Study objectives

To investigate and analyze the effect of neoadjuvant chemotherapy on paraneouterine metastasis and postoperative treatment of cervical cancer

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/11/2018, Ethics Committee of Tongji Medical College, Huazhong University of Science and Technology (Hangkong Road, #13, Qiaokou District, Wuhan, China; +86 027 83691785; tongjilunli@163.com), ref: S452

Primary study design

Observational

Study design

Single-center retrospective cohort study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Feasibility of NACT in localized advanced cervical cancer patients

Interventions

The NACT group: FIGO(2009) IB2-IIA2 cervical cancer patients underwent carboplatin-liposomal paclitaxel chemotherapy followed by radical hysterectomy and pelvic lymphadenectomy.

The PRS group: FIGO(2009) IB2-IIA2 cervical cancer patients underwent primary radical hysterectomy and pelvic lymphadenectomy.

For NACT, carboplatin-paclitaxel carboplatin-liposomal paclitaxel regimen was used. Patients intravenously received paclitaxel at 135-175 mg/m² on the first day and carboplatin at an area under the curve (AUC) = 5 on the second day every 3 weeks. The number of NACT cycles ranged from 2 to 3.

For radical hysterectomy, surgical procedures were performed according to the C type of the Querleu-Morrow classification. Systematic bilateral pelvic lymphadenectomy including the common iliac, external iliac, internal iliac, obturator regions, and parametric lymph nodes were removed.

The follow up was performed according to the recommendations from National Comprehensive Center Network. The items mainly included gynaecological examination, vaginal stump cytological examination, pelvic ultrasound, and chest X-ray.

Intervention Type

Mixed

Primary outcome(s)

5-year overall survival defined as the time from completion of operation to death or to the date of last contact.

Key secondary outcome(s)

1. 5-year progression-free survival defined as the time from completion of operation to the first appearance of progressive disease or to the date of last contact
2. Cumulative postoperative radiation rate: use of radiation and the interval between surgery and radiation (adjuvant therapy or therapy after recurrence) were used to estimate the cumulative radiation during the follow-up

Completion date

01/05/2021

Eligibility

Key inclusion criteria

1. Primary malignant tumor of cervix confirmed by cervical biopsy
2. No other malignant tumors

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

414

Key exclusion criteria

1. Cervical metastatic malignant tumor
2. Complicated with other malignant tumors
3. Patients undergoing surgery or pathological examination in other hospitals

Date of first enrolment

01/01/2019

Date of final enrolment

01/01/2021

Locations

Countries of recruitment

China

Study participating centre

Union Hospital, Tongji Medical College, Huazhong University of Science and Technology

Jiefang Avenue #1277

Wuhan

China

430022

Sponsor information

Organisation

Union Hospital, Tongji Medical College, Huazhong University of Science and Technology

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
zehuawang@hust.edu.cn

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/08/2022	23/08/2022	Yes	No