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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

Registration date
13/07/2022

Overall study status
Completed

Last Edited
23/08/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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

Study design
Single-center retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not applicable (retrospective study)

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 measure

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

Secondary outcome measures
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

Overall study start date
01/01/2018

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

Age group
Adult

Sex
Female

Target number of participants
207

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
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Sponsor information

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.whuh.com

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2022

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