ISRCTN50443832 https://doi.org/10.1186/ISRCTN50443832

Blocking the descending branch of uterine artery in cervical conization

Submission date	Recruitment status	[X] Prospectively registered
15/09/2013	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
15/10/2013	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
16/10/2013	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cervical cancer is the third most common gynecological cancer but the stage called Cervical intraepithelial neoplasia (CIN) is curable with resection. Screening tests have become more common and are the main way of preventing cervical cancer. The microscopic examination of cells scraped off the cervical epithelium (Pap smear test) gives important screening information and grades CIN from 1 to 3. The removal of a cone-shaped section of the cervix with a blade (called a cold knife conization) is the main surgical procedure for premalignant lesions of the cervix, especially for those young patients who wish to have children later.
Bleeding is an important aspect of the procedure. The descending branch of the uterine artery is the main blood supply for the cervix. Conization normally takes about 10-15 minutes, so blocking the descending branch of uterine artery temporarily may be a simple but convenient, effective and safe way of reducing bleeding and facilitating the procedure. This is the aim of the study.

Who can participate?
Our trial aims to recruit about 100 female patients in the Department of Obstetrics and Gynecology of Shengjing Hospital, aged between 18 and 65, who have CIN2 with a large area of lesion or invading the glands, or who have CIN3 and want to have children.

What does the study involve?
The study will involve 100 female patients who will randomly allocated to one of two groups: a control group or an experimental group. The control group will receive conventional cold knife conization only. The experimental group will receive cold knife conization and blocking of the descending branch of uterine artery
During the procedure, we will compare the amount of blood loss in each group. After the operation and at follow-up, we will compare the cure rate, recurrence rate, and the rate of complications (such as abnormal post-operative bleeding, infection, bladder injury, incompetent cervix and cervical stenosis) in each group.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But patients in the experimental group will benefit from the modification of the procedure (less blood loss, shorter operation time and fewer post-operative complications). This may also help standardize cold knife

conization.
Risks involve damage to the arterial branches by mistake, leading to bleeding and hematomas and damage to the bladder but measures are in place to minimize such risks.

Where is the study run from?
This study has been set up by the Department of Obstetrics and Gynecology of Shengjing Hospital of China Medical University (China).

When is the study starting and how long is it expected to run for?
The study will start in November 2013 and will run for 8 months, or until the required number of 100 participants have been recruited. The study will continue as we follow up participants long-term prognosis and complications.

Who is funding the study?
New Technology Project of Shengjing Hospital of China Medical University (China).

Who is the main contact?
Professor Dan-Bo Wang
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Contact information

Type(s)
Scientific

Contact name
Prof Dan-Bo Wang

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110004

Additional identifiers

Study information

Scientific Title
Blocking the descending branch of uterine artery in cervical conization: a randomized controlled trial

Study objectives
Blocking the descending branch of uterine artery temporarily is an effective measure to reduce bleeding and to facilitate surgery during cold knife conization of the cervix.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Ethics Committee of Shengjing Hospital of China Medical University

Primary study design
Interventional

Study design
Prospective randomized trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cervical intraepithelial neoplasia

Interventions
Blocking the descending branch of uterine artery.The study will involve 100 female patients who will be randomized to either a control group or an experimental group:

1. The control group will receive conventional cold knife conization only.
2. The experimental group will receive cold knife conization and blocking of the descending branch of uterine artery.

Follow-up is required for all participants. Repeat Pap smears, colposcopy and HPV DNA testing are carried out 2 months after the operation. Pap smear and HPV DNA testing are carried out every 6 months for 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Hemorrhage during surgery measured by evaluating the volume (ml) of blood loss during procedure

Key secondary outcome(s)
1. Operation time
2. The cure rate at follow-up
3. The recurrence rate at follow-up
4. The rate of postoperative complications: abnormal post-operative bleeding, infection, bladder injury, incompetent cervix and cervical stenosis

Completion date
01/07/2014

Eligibility

Key inclusion criteria

All cases that meet the criteria for cold knife conization:
1. Patients who have CIN2 with a large area of lesion or invading the glands
2. Patients who have CIN3 and want to have children

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients with contraindications
2. Patients who have previously undergone cervical surgery (which has an impact on the anatomy of the cervix and the ureter)

Date of first enrolment
01/11/2013

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
China

Study participating centre
Department of Obstetrics and Gynecology
Shenyang
China
110004

Sponsor information

Organisation
Shengjing Hospital of China Medical University (China)

ROR
https://ror.org/0202bj006

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
New Technology Project of Shengjing Hospital of China Medical University, China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration