

# Evaluation of postoperative sexual, urinary and bowel function in women with early stage cervical cancer after nerve sparing radical trachelectomy versus vaginal radical trachelectomy

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To compare sexual functioning and complaints concerning micturation and defecation in women after abdominal or vaginal trachelectomy for early stage cervical cancer.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Reproductive neoplasms male malignant and unspecified
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON32881

### Source

ToetsingOnline

### Brief title

Late complications after abdominal or vaginal trachelectomy

### Condition

- Reproductive neoplasms male malignant and unspecified
- Uterine, pelvic and broad ligament disorders
- Obstetric and gynaecological therapeutic procedures

### Synonym

cancer of the cervix, cervical cancer

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cervical cancer, quality of life, seksual function, surgery

## Outcome measures

### Primary outcome

Sexual functioning and complaints of micturation and defecation according to the validated questionnaires.

### Secondary outcome

NA

## Study description

### Background summary

Sexual, micturation and defecation disorders are well known postoperative complaints following radical hysterectomy in women with cervical cancer. Damage to the autonomic innervation of bladder, rectum and vagina (the hypogastric nerve and plexus) may be the leading cause of these disorders. Maas et al showed significant damage to the autonomic nerves in conventional radical hysterectomy at the cleavage site of the sacro-uterine ligament. Yabuki et al were the first to perform a nerve sparing radical hysterectomy. This modified radical hysterectomy appears to be safe in the sense of disease free survival. Following nerve sparing surgery women have significantly less urinary complaints and Pieterse showed that the vaginal response on sexual stimulation (as an objective measure of function of the hypogastric nerve) is less impaired after nerve sparing radical hysterectomy when compared to women after conventional radical hysterectomy.

Radical trachelectomy can be used to treat women with early stage cervical cancer who wish to preserve fertility because the uterine body is left in situ while the uterine cervix with surrounding tissue as in radical hysterectomy (including sacro-uterine ligament with the hypogastric nerve and plexus). This

surgical procedure can be performed vaginally or abdominally. In case of abdominal trachelectomy the autonomic nerves can be saved as in nerve sparing radical hysterectomy, while in vaginal trachelectomy it is not possible to selectively save the autonomic nerves. Until now it is unclear if there is a difference in sexual functioning and complaints concerning micturation and defecation after abdominal versus vaginal trachelectomy. In theory abdominal trachelectomy saves the autonomic nerves and this may result in less complaints. On the other hand vaginal trachelectomy may not damage the autonomic nerves because of different approach as compared to the abdominal route, moreover vaginal trachelectomy results in less intraabdominal adhesions and does not leave a large surgical scar on the abdomen with possible negative effect on self-esteem en sexual functioning.

### **Study objective**

To compare sexual functioning and complaints concerning micturation and defecation in women after abdominal or vaginal trachelectomy for early stage cervical cancer.

### **Study design**

The study is a questionnaire - study. Women who underwent abdominal or vaginal trachelectomy will be asked to participate. Participating women are asked to fill out three validated questionnaires: EORTC QLQ-C30 (cancer specific quality of life questionnaire, EORTC QLQ-CX24 (cervical cancer specific quality of life questionnaire and the Gynecologic Leiden Questionnaire (cervical cancer specific questionnaire for sexual and pelvic floor symptoms). Copyright holding authorities have approved the use of the questionnaires. The results of the questionnaires will be compared according to surgical procedure.

### **Study burden and risks**

No risk, minimal burden (3 questionnaires, approx 30 minutes) with possible quality of life benefit for women who need to be treated for early stage cervical cancer and wish to preserve fertility.

## **Contacts**

### **Public**

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## Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Early stage cervical cancer (FIGO stage 1a-1B1)

Abdominal or vaginal trachelectomy

### Exclusion criteria

Adjuvant therapy (eg radiation therapy and /or chemotherapie)

Local recurrence and / or distant metastasis

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-03-2010  
Enrollment: 40  
Type: Actual

## Ethics review

Approved WMO  
Date: 25-02-2010  
Application type: First submission  
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL30837.058.09