Pretherapeutic para-aortic lymphadenectomy in advanced stage cervical cancer.

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1. To study the safety and feasibility of para-aortic surgical staging in advanced cervical cancer in the Netherlands.2. To provide insight in the possible effectiveness of para-aortic surgical staging in advanced cervical cancer as compared to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON40720

Source
ToetsingOnline

Brief title
PALDISC

Condition

- Metastases
- Cervix disorders (excl infections and inflammations)
- Obstetric and gynaecological therapeutic procedures

Synonym
Cervical cancer metastases, metastatic cancer of the cervix

Research involving
Human

Sponsors and support

Primary sponsor: Operatiekamers

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

Intervention

Keyword: Cervical cancer, lymphadenectomy, para-aortic, Staging

Outcome measures

Primary outcome

The main study parameter is the safety and feasibility of para-aortic surgical staging. This will be assessed by registering proportion of included patients amongst all eligible patients. Furthermore by registering duration of surgical procedure, blood loss, complications and adverse events.

Nodal yield will be compared to results found in other studies in order to assess completeness of lymphadenectomy.

Secondary outcome

Data on sensitivity, specificity, negative and positive predictive value of MRI, PET-CT and surgical staging will be gathered to base power calculations for a future independent phase 3 trial.

The amount and diameter of metastases and proportion of modified initial treatment plans for adjuvant therapy, due to histological findings will be documented.

Morbidity and mortality, Quality of life (QLQ-C30 version 3.0, QLQ-CX24) and progression-free and overall survival during the first year after surgery will be compared between treatment arms. Treatment delay due to surgical intervention and histological analyses will be compared. Time to treatment will

be measured from the day of randomization until start of chemo radiation.

Study description

Background summary

In the Netherlands, surgical staging of para-aortic lymph nodes in advanced cervical cancer is not common practice. This study will assess safety and feasibility of surgical staging in advanced cervical cancer in the Netherlands. It will provide insight in detection rate of micro metastases, and upstaging of radio therapeutic treatment plan due to surgical staging. This information will be used to assess the necessity for a Dutch phase 3 study on surgical staging as well as provide vital information for the power-analysis of this phase 3 study.

Study objective

1. To study the safety and feasibility of para-aortic surgical staging in advanced cervical cancer in the Netherlands.
2. To provide insight in the possible effectiveness of para-aortic surgical staging in advanced cervical cancer as compared to current standard of care with regard to detecting metastases and postoperative morbidity, mortality, quality of life, (and survival).

Study design

A phase 2 randomized controlled multicenter trial at the Radboudumc, Maastricht University Medical Center and Gynaecological Oncology Centre South.

Intervention

Para-aortic lymphadenectomy will be added to standard of care and imaging (CT, MRI and/or Pet-CT) for locally advanced cervical cancer.

Study burden and risks

The intervention group will undergo additional laparotomic, laparoscopic or robot-assisted trans- or retroperitoneal para-aortic lymphadenectomy. Intra-operative complications may be bowel, bladder, nerve, and vessel injury. This may sometimes leadto a conversion to laparotomy. The percentage of patients with significant morbidity is around 10%, mostly consisting of a post operative lymphocele, infection and delayed wound healing. However, in general, the complications of a para-aortal lymphadenectomy do not delay

completion of cervical cancer treatment. Therefore, it is hypothesized that performing a para-aortal lymphadenectomy before concomitant chemo-radiotherapy may result in an adjusted treatment plan, leading to better loco-regional control of the disease and subsequently improves survival and quality of life. Furthermore the intervention group will undergo standard PET-CT. This might lead to an additional visit. There is however no additional risk associated with PET-CT and it can be considered standard of care.

Contacts

Public
Selecteer

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Selecteer

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age * 18 years
Histologically confirmed squamous cell, adenosquamous or adenocarcinoma of the cervix
Stage IB2 , IIA with tumor > 4cm,IIB, IIIA, IIIB, IVA, staging performed as examination under

anesthesia (EUA).
WHO-performance 0-2
No evidence of distant metastasis
Fit for surgery
Written informed consent

Exclusion criteria

Previous malignancy (except for non-melanoma skin cancer)
Prior retroperitoneal surgery
Previous pelvic or abdominal radiotherapy
Upper abdominal intraperitoneal disease or evidence of ovarian metastasis
Evidence of distant metastasis on imaging or physical examination
Bulky para-aortic lymph nodes > 2cm
Pregnancy
Otherwise unfit for surgery

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	29-07-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28637
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49310.091.14
OMON	NL-OMON28637