Pretherapeutic surgical staging of para-aortic lymph nodes in advanced stage uterine cervical cancer.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28637

Source
Nationaal Trial Register

Brief title
PALDISC

Health condition

Advanced stage uterine cervical cancer, surgical staging, para-aortic lymph node metastases

Gevorderd cervixcarcinoom, chirurgisch stadiëren, para aortale lymfklier metastasen

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Radboudumc

Intervention

Outcome measures

Primary outcome

-Proportion of included patients amongst all eligible patients.

-Duration of surgical procedure

-Blood loss

-Complications

-(serious) Adverse events

-Nodal yield

Secondary outcome

Data on sensitivity, specificity, negative and positive predictive value for a future independent phase 3 trial.

Number and diameter of metastases and proportion of modified initial treatment plans due to histological findings.

Morbidity and mortality, Quality of life and progression-free and overall survival during the first year after surgery.

Treatment delay due to surgical intervention and histological analyses.

Study description

Study objective

Imaging modalities such as computed tomography (CT), positron emission tomography (PET), and magnetic resonance imaging (MRI) are limited by low sensitivity and specificity to detect para-aortic lymph node metastases in advanced stage cervical cancer when compared with surgical staging. Para aortic lymph node status is the most important prognostic factor, together with tumour stage.

This study will assess safety and feasibility of surgical staging in locally advanced cervical cancer in the Netherlands.

Study design

-Diagnostic biopsy, within 6 weeks of surgery

- EUA within 6 weeks of surgery

- FIGO staging within 6 weeks of surgery

- chest x-ray and/or CT scan, and/or pelvic MRI, and Pet-CT within 6 weeks of surgery

- Quality of Life (QLQ-C30 version 3.0, QLQ-CX24), at inclusion, 2 and 6 weeks after surgical staging, and 3, 6, and 12 months after start treatment.

Intervention

Para-aortic lymphadenectomy

Contacts

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Eligibility criteria

Inclusion criteria

-Age > 18 years

-Histological 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

-WBC > 3.0x 109/L, platelets > 100 x 109/L, creatinine clearance > 60ml/min

-Chest CT or X-ray, abdominal MRI, or CT scan, and PET-CT with no evidence of distant metastasis

-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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-11-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40720
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4782
NTR-old	NTR4922
CCMO	NL49310.091.14
OMON	NL-OMON40720

Study results