Lymphatic mapping for image guided radiotherapy in patients with locally advanced cercical cancer, a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22806

Source
NTR

Brief title
LaMA

Health condition

uterine cervical cancer

Sponsors and support

Primary sponsor: Amsterdam University Medical Center University of Amsterdam
Source(s) of monetary or material Support: AMC Foundation

Intervention

Outcome measures

Primary outcome

Feasibility of the lymphatic mapping procedure in locally advanced cervical cancer

Secondary outcome

Agreement of the lymphatic map with the radiotherapy treatment plan including previous imaging (MRI / CT / FDG-PET/CT)

Study description

Background summary

Lymph node metastasis is an important unfavourable prognostic factor in locally advanced cervical cancer (LACC), thus preferably all lymph nodes with metastases should be included in the radiotherapy treatment plan. At our institution, the radiotherapy treatment plan consists of external beam radiotherapy of the pelvis, extended to the para-aortal region if there are evidently suspicious lymph nodes on imaging, histopathologically proven when feasible. An extra boost is given to the parametria when there is suspicion of parametrium involvement on imaging and/or during investigation under anaesthesia, and to suspicious lymph nodes. External beam radiotherapy is followed by additional brachytherapy to the primary tumour.
If no lymphadenectomy is performed, it can be challenging to prove lymph node metastases on imaging, especially micrometastases. Early recurrence of cervical cancer occurs most of the time in lymph nodes. This suggests that in a patient with lymph node recurrence, the radiation treatment was suboptimal: the nodes with recurrent disease were either not included in the radiation treatment plan or did not receive a sufficient radiation dose.
Lymphatic mapping is a procedure in which all lymph nodes with drainage from the primary tumor, i.e. all nodes with potential (micro)metastases, can be imaged. These nodes are not necessarily suspicious on other imaging techniques.
Objective:
The goal of this pilot study is to
1. investigate the feasibility of the lymphatic mapping procedure in locally advanced cervical cancer
2. study the agreement of the lymphatic map with the radiotherapy treatment plan including previous imaging (MRI / CT / FDG-PET/CT)

Study objective

1. It is feasible to perform lymphatic mapping in locally advanced uterine cervical cancer. 2. There are lymph nodes on the lymphatic map which are not included in the radiation treatment plan or did not receive sufficient radiation dose.

Study design

Start date 20-07-2020.
Primary outcome: After completion of the 2nd lymphatic map imaging (1 day after inclusion). Method: visual assessment. Visualisation of lymph nodes on both sides of the tumor is considered a positive outcome. Visualised nodes are nodes at risk.
Secondary outcome: After inclusion of all patients.

Method: the details of the RT treatment plan (location and dose of RT on lymph nodes; blinded to the lymphatic map) is retreived from the electronical patient chart. The RT data will be compared to the localisation of nodes at risk on the lymphatic map.

Contacts

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Eligibility criteria

Inclusion criteria

Histologically proven locally advanced cervical cancer [FIGO stage IIB-IVA].
>18 years old.
Treatment with curative (chemo)radiation.
Signed informed consent.

Exclusion criteria

Pregnancy.
Administration of the radioactive tracer cannot be ensured properly due to obesity.
Patients with tumors in which no circumferential injection of [99mTc]Tc-nanocolloid is possible due to the size or position of the tumor.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-07-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55075
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9323
CCMO	NL73563.018.20
OMON	NL-OMON55075

Study results