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

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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. Are all lymph nodes at risk...

Ethical review	Approved WMO
Status	Completed
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON55075

Source
ToetsingOnline

Brief title
LaMA

Condition

- Miscellaneous and site unspecified neoplasms benign
- Cervix disorders (excl infections and inflammations)

Synonym
locally advanced cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC Foundation - anoniem vermogensfonds

Intervention

Keyword: image guided radiotherapy, locally advanced cervical cancer, lymphatic mapping, radiotherapy

Outcome measures

Primary outcome

Is it feasible to perform lymphatic mapping in locally advanced cervical

cancer?

Is there visualisation of (multiple) lymph nodes in both sides of the tumour?

Secondary outcome

Are all visible lymph nodes included in the standard radiotherapy treatment

plan?

Did all visible lymph nodes receive the intended curative dose?

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 (MRI, [18F]FDG-PET/CT), 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 modified sentinel node procedure. During this procedure

all lymph nodes with drainage from the primary tumor, i.e. all nodes with potential (micro)metastases, can be imaged with an aid of a radiopharmaceutical. These nodes are not necessarily suspicious on other imaging techniques. When performing the lymphatic mapping, information is gained about the individual pattern of lymph node draindage.
In our study we will compare the lymphatic map to the standard radiation treatment plan.
Our future goal is to investigate if the lymphatic map can aid the finetuning of the radiotherapy treatment plan. In case of a positive outcome of this pilot we are planning to set up a larger prospective study. Lymphatic mapping can be a new approach to personalized image guided radiotherapy, when dose escallation and de-escallation is based on the individual lymphatic map.

Study 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. Are all lymph nodes at risk are included in the radiotherapy treatment plan and receive a sufficient (curative) dose as intended?

Study design

A pilot study with 40 consecutive patients.

Study burden and risks

1. There is a limited radiation burden of the lymphatic mapping procedure. A total of 6-8 depots of 35MBq [99mTc]Tc-nanocolloid will be administered peritumorally. The radiation burden of of the administration of the [99mTc]Tc-nanocolloid is maximal 0,8 mSv. The radiation burden of the low dose CT, performed as part of the two SPECT-CT investigations of the abdomen is 2 x 1,9 mSv. Thus the maximal total radiation burden is 4,6 mSv. This is approximately twice the range of the natural background radiation in the Netherlands (~2,5 mSv) and negligible compared to the radiation burden of the curative radiotherapy in this study population (46 to 90Gy).
2. Minimal bleeding can be expected after administration of the radiopharmaceutical, especially in case of highly vascularized tumors. However, considering that injections will be done peritumoral and not intratumoral, the risk of bleeding is limited.
There are no other known risks of the lymphatic mapping procedure. Patients are still under anaesthesia when injecting the [99mTc]Tc-nanocolloid, thus will not have any discomfort during injection.
3. Anaesthesia time will be elongated with approximately 8-10 minutes. This has

in general no health hazard in this population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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

BMI and pregnancy.
Administration of the radioactive tracer cannot be ensured properly due to obesity (BMI >35).
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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-07-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-02-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 22806
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL73563.018.20

Study results

Date completed: 19-07-2022

Results posted: 13-08-2023

First publication
12-06-2023