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

Gepubliceerd: 04-03-2021 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22806

Bron
Nationaal Trial Register

Verkorte titel
LaMA

Aandoening

uterine cervical cancer

Ondersteuning

Primaire sponsor: Amsterdam University Medical Center University of Amsterdam
Overige ondersteuning: AMC Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility of the lymphatic mapping procedure in locally advanced cervical cancer

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-07-2020
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55075
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten