CONCERV Studie

Gepubliceerd: 17-03-2017 Laatst bijgewerkt: 18-08-2022

To evaluate the safety and feasibility of performing conservative surgery in women with stage IA2 or IB1 carcinoma of the cervix with favorable pathologic features

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24972

Bron
NTR

Verkorte titel
CONCERV

Aandoening

Stage IB1 cervical cancer,

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: MD Anderson, Houston, Texas, USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Immediate Failure Rate [Time Frame: 5 Years]
The immediate failure rate is defined as residual disease in the simple hysterectomy specimen.

Toelichting onderzoek

Achtergrond van het onderzoek

Radical hysterectomy with pelvic lymph node dissection is the current standard for the treatment of early stage cervical cancer. While this is an effective treatment, it is associated with morbidity due to removal of the parametrium, which contains autonomic nerve fibers associated with bladder, bowel and sexual function. Several retrospective studies have shown that in early stage cervical cancer with favorable pathologic characteristics, the parametrial involvement is only 0 to 0.6%.

Primary Objective:

1. To evaluate the safety and feasibility of performing conservative surgery in women with stage IA2 or IB1 carcinoma of the cervix with favorable pathologic features

Secondary Objectives:

1. To estimate the cervix cancer recurrence rate at 2 years in women treated with conservative surgery for stage IA2 or IB1 carcinoma of the cervix with favorable pathologic features

2. To compare pelvic lymph node involvement in patients undergoing conservative surgery with historical data from matched patients treated with radical hysterectomy

3. To estimate the sensitivity of sentinel lymph node biopsy in the determination of pelvic lymph node metastases in this group of patients

4. To compare the treatment-associated morbidity in patients undergoing conservative surgery with historical data from matched patients treated with radical hysterectomy

5. To assess quality of life factors, sexual functioning, symptoms and satisfaction with healthcare decisions in this group of patients

Doel van het onderzoek

To evaluate the safety and feasibility of performing conservative surgery in women with stage IA2 or IB1 carcinoma of the cervix with favorable pathologic features

Onderzoeksopzet

01-04-2017-01-09-2018

Onderzoeksproduct en/of interventie

This is a prospective, multi-institutional cohort study evaluating the outcomes of performing conservative surgery in women with stage IA2-IB1 cervical cancer with favorable pathologic characteristics. Up to 195 total patients will be enrolled to this study in order to accrue 100 evaluable patients.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Histologically confirmed squamous cell carcinoma of the cervix (any grade) or Histologically confirmed grade 1 or 2 adenocarcinoma of the cervix

2. FIGO stage IA2 or IB1 disease

3. Tumor diameter <2 cm on physical exam and on imaging studies (if performed)

4. No lymphovascular space invasion (LVSI) present on biopsy or previous cone

5. Less than 10mm of cervical stromal invasion

6. Cone margins and endocervical curettage (ECC) specimen negative for invasive cancer, cervical intraepithelial neoplasia (CIN) CIN II, CIN III or adenocarcinoma-in-situ. (A negative margin is defined as no invasive cancer within 1.0mm of both the endocervical and ectocervical margins and no AIS or CIN II or CIN III at the inked or cauterized margin; one repeat cone and ECC permitted)

7. Patients are eligible for the study when a cone and ECC are performed prior to pre-enrollment in the study, and pathologic eligibility criteria are met. The cone and ECC must be performed within 12 weeks prior to pre-enrollment in the study. If the cone and ECC performed prior to pre-enrollment do not meet the pathologic criteria, patients may be pre-enrolled and are allowed 1 repeat cone & ECC after pre-enrollment in order to meet pathologic eligibility criteria. (see section 6.1)

8. Patients must sign an approved informed consent document

9. If patient is of childbearing potential, she must have a negative blood or urine pregnancy test within 14 days of surgical treatment on study.

10. Imaging with Positron emission tomography (PET) scan, computed tomography (CT) scan of the abdomen and pelvis, and/or magnetic resonance imaging (MRI) of the abdomen and pelvis must be performed and negative for metastatic disease within 12 weeks of enrollment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clear cell, neuroendocrine, adenosquamous, serous carcinoma or other high-risk histologies

2. Grade 3 adenocarcinoma

3. FIGO stage IA1, IB2, II, III or IV disease

4. Tumors >2 cm in diameter on physical exam or imaging studies

5. Presence of LVSI

6. Greater than or equal to 10mm of cervical stromal invasion

7. Cone margins or ECC specimen positive for invasive cancer, CIN II, CIN III or

adenocarcinoma-in-situ (one repeat cone permitted)

8. Neoadjuvant radiation therapy or chemotherapy for cervical cancer

9. Patients unwilling or unable to provide informed consent for the study

10. Evidence of metastatic disease on PET, CT, and/or MRI performed within 12 weeks of enrollment

11. Patients who have had a simple hysterectomy (cut through hysterectomy)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-04-2017
Aantal proefpersonen:	10
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6124
NTR-old	NTR6263
Ander register	: NCT01048853

Resultaten