FIGO 2018 stage IB2 (>2cm - <=4 cm) Cervical Cancer Treated with Neoadjuvant Chemotherapy Followed by Fertility Sparing Surgery (CoNteSSa) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F)

Published: 14-12-2020
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This study has been transitioned to CTIS with ID 2023-507230-24-00 check the CTIS register for the current data. To assess the feasibility of preserving fertility in women with 2018 FIGO stage IB2 cervical cancer with lesions measuring >2 cm -

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54356

Source
ToetsingOnline

Brief title
CONTESSA/NEOCON

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cervical cancer, cervical carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Princess Margaret Cancer Centre
Source(s) of monetary or material Support: KWF

Intervention

Keyword: cervical cancer, conservative surgery, fertility, neo-adjuvant chemotherapy

Outcome measures

Primary outcome

to determine the rate of functional uterus defined as successful fertility

sparing surgery (FSS) with no adjuvant therapy

Secondary outcome

response rate based on RECIST 1.1 following neoadjuvant chemotherapy

safety of the fertility sparing surgery (FSS)

overall survival (OS)

Study description

Background summary

The standard treatment of stage Ib2 2-4 cm cervical cancer in women who wish to preserve fertility is an abdominal radical trachelectomy with pelvic lymph node dissection. Since the number of take home babies after completing this procedure is below 10%, there is a need for exploration of alternative treatment modalities with better chances of preserving fertility at equal risk of recurrence.

Study objective

This study has been transitioned to CTIS with ID 2023-507230-24-00 check the CTIS register for the current data.

To assess the feasibility of preserving fertility in women with 2018 FIGO stage IB2 cervical cancer with lesions measuring >2 cm - <=4 cm.

Study design

This is a prospective, multi-center phase II open label non-randomized trial evaluating the outcomes of performing less radical surgery in women with stage Ib2 2-4 cm cervical cancer with no pelvic lymph node metastases and adequate response to neo-adjuvant chemotherapy, who wish to preserve their fertility

Intervention

If no metastases are observed, patients will start a short protocol of three courses of weekly neo-adjuvant chemotherapy (9 weeks). If response to chemotherapy results in a tumor of less than 2 cm, cervical conisation or a simple trachelectomy/portio amputation with application of a cerclage will be performed

Study burden and risks

Burden: Patients will undergo a sequential treatment of surgery (pelvic lymph node dissection), followed by neo-adjuvant chemotherapy and conisation. This process takes several months and is more time consuming than the current standard treatment of radical abdominal trachelectomy with pelvic lymph node dissection in one session. Patients will be asked to fill in QoL questionnaires at 9 time points in this trial.

Risk: recurrence of disease, short-term and long-term side effects of chemotherapy (bone marrow depression, opportunistic infections, neurotoxic side effects, reduced fertility).

Benefit: women are expected to have better chances to become pregnant and have less immature and premature deliveries. Due to less radical surgery, women are expected to have less side effects on rectal-, bladder and sexual function.

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

Patients must have histologically confirmed invasive cervical cancer with adenocarcinoma, adenosquamous or squamous histology and FIGO 2018 IB2 measuring >2 cm - <=4 cm

Patients must be >=18 years of age, and < 40 years of age

Patients must be premenopausal and wish to preserve fertility

no prior therapy to treat their cancer lesion, patients with diagnostic cone or LEEP are allowed but a measurable tumor of >2 cm - <=4 cm is mandatory

Eastern Cooperative Group (ECOG) performance status <= 2

Within 7 days of the proposed start of treatment, patients must have normal organ and marrow function

No evidence of active uncontrolled infection

Patient must have disease that is measurable per RECIST 1.1.

Ability to understand and willing to sign a written informed consent document.

A negative serum pregnancy test

Exclusion criteria

Patients who are receiving any other investigational agents.

Patients with other cancers requiring ongoing treatment.

Patients with known / evidence of brain metastases

Uncontrolled inter-current illness

Patients who are pregnant or breastfeeding

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-04-2021
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Carboplatin Hospira

Generic name:	Carboplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Paclitaxel Hospira
Generic name:	Paclitaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-12-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	02-02-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	26-03-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-04-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-09-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-01-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-02-2023

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-03-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EU-CTR	CTIS2023-507230-24-00
EudraCT	EUCTR2020-000404-11-NL
ClinicalTrials.gov	NCT04016389
CCMO	NL72658.031.20