Molecular Markers in the Treatment of Endometrial Cancer 2

Published: 04-10-2017
Last updated: 13-04-2024

Primary objectives:MoMaTEC2 aims to test the applicability of already identified and promising molecular biomarkers ER and PR, to improve risk stratification and individualisation of treatment for patients with EC.Secondary objectives:To perform a...

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

Summary

ID

NL-OMON49578

Source
ToetsingOnline

Brief title
MoMaTEC 2

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cancer of the womb, Endometrial carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Haukeland University Hospital
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Endometrial neoplasms, Estrogen receptor, Lymphadenectomy, Progesteron receptor

Outcome measures

Primary outcome

Presence of lymph node metastasis

Secondary outcome

Prognostic impact (overall survival, disease specific survival, recurrence-free

survival)

Quality of life

Study description

Background summary

Endometrial cancer (EC) is the most common pelvic gynaecological disease in the western world. Low-risk patients with localized disease face good prognosis and can often be treated with surgery alone. Current risk classification in EC is based on the International Federation of Gynecology and Obstetrics FIGO stage, tumor subtype and histological grade. Yet, 20% of those tumors with estimated low-risk will recur and up to 50% of those with high-risk do not. Standard treatment of EC is based on preoperative risk stratification, and consists of hysterectomy and bilateral salpingo-oophorectomy for low-risk (grade 1 or 2) EC, and additional lymphadenectomy for high-risk (grade 3) EC. Based on data of the MoMaTEC1 series, it was demonstrated that additional immunohistochemical analysis of estrogen receptor (ER) and progesterone receptor (PR) preoperatively, improved the currently used risk stratification both with respect to lymph node metastasis and poor prognosis. The percentage of lymph node metastasis was shown to increase from 8% in patients with preoperatively low-grade histology and positive expression of hormone receptors, to 15.4% in patients with low-grade histology and loss of either ER/PR, compared to 23% for patients with loss of either ER/PR regardless of histology. Implementing hormone receptor status to improve risk stratification for selecting high-risk patients likely to benefit from lymphadenectomy seems justified.

Study objective

Primary objectives:
MoMaTEC2 aims to test the applicability of already identified and promising molecular biomarkers ER and PR, to improve risk stratification and individualisation of treatment for patients with EC.

Secondary objectives:
To perform a phase 4 implementation trial for optimized stratification of surgical treatment, specifically the performance of (para-aortic and pelvic) lymphadenectomy guided by expression of ER and PR. In this way, to improve identification of those at risk for lymph node metastasis and poor outcome. Moreover, to give a foundation for a more homogenous practice of preoperative risk stratification and surgical treatment of endometrial cancer among different centers in Europe.
To investigate the impact of peri-operative morbidity by determination of quality of life with structured and validated endometrial cancer-specific questionnaires.
To collect additional tissues for identification and validation of novel prognostic markers.

Study design

Prospective multicenter interventional study

Intervention

Low-risk patients will undergo a hormone-receptor guided lymphadenectomy, in addition to standard hysterectomy and salpingo-oophorectomy. This will be performed according to the local protocols, which means a pelvic and lower para-aortic (up to to arteria mesenterica inferior) lymphadenectomy.

Study burden and risks

Possible discomforts and risks:
1.Due to the lymphadenectomy procedure, approximately 7% of patients may get lymphedema or lymphocele in varying degree and discomfort. Assuming an increase of 11.3% in lymphadenectomies, an additional 1% of patients will experience these side-effects.
2.Patients will fill out a number of quality of life questionnaires preoperatively and during follow up and provide some specific information related to prior medication and obesity related factors. These questionnaires will take approximately 30 minutes to fill out.
3.Due to the increased detection of lymph node metastasis, there will be an increased need for systemic therapy. With an expected prevalence of 15.4% lymph node metastasis in this group, an additional 1.7% will be recommended to receive systemetic therapy, with subsequently possible side-effects, but with an increased disease specific survival.

4.The collection of tissue for the biobank consists of collecting two blood samples, urine, an additional endometrial biopsy, and frozen tumor tissue, and will be performed intra-operative, when the patient is under general anesthesia. In this way, no extra burden on the patients is expected.

Possible advantages:
1.We expect a decrease in false negative low-risk stratification for patients resulting in more correct stratification of high-risk patients to the high-risk group with appropriate clinical management for this population.
2. Due to a better risk stratification and resulting treatment consequences one hopes to note an increase of 5-year life expectancy and a reduction in (systemic) recurrence rate in the population.
3.Through systematic appraisal of their quality of life, focusing on endometrial cancer related issues, patients may hopefully take up symptoms more easily with their treating physician

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

All patients with a diagnosis of endometrial cancer, histologically proven by means of preoperative endometrial sampling.

Exclusion criteria

Patients who will or cannot give informed consent (including language barriers)
Patients <18 years of age
Patients who will not receive surgical treatment for their endometrial cancer

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2017
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2017

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-03-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-07-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-01-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-10-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-06-2021

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL60759.091.17