PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Prospective, European collaborative multicenter observational study of standardized, ontogenetically based radical surgery in endometrial cancer FIGO IAG3 and stage IB to III by peritoneal mesometrial resection and therapeutic lymphadenectomy (PMMR/tLNE) without additional radiotherapy

Trial Acronym

PMMR-Study

URL of the trial

[---]*

Brief Summary in Lay Language

Endometrial Cancer is currently usually treated by hysterectomy. Depending from the stage of disease, either no or all lymph nodes in the pelvis and the aortic region are removed. Following surgery, radiotherapy is often used to prevent local recurrence.
The technique of PMMR + TCL aims at
a) treating the disease so effectively by removal of the uterus and the adjacent tissue alone, that radiotherapy can be omitted and
b) removing the so-called sentinel lymph nodes in all patients to perform complete lymphadenectomy only in patients with involved nodes.
The study is a purely observational study.

Brief Summary in Scientific Language

Current situation: Standard therapy of endometrial cancer consists of hysterectomy and bilateral salpingoovarectomy. In low-risk cases, current guidelines do not recommend lymphadenectomy. In intermediate/high risk cases, complete pelvic/paraaortic lymphadenectomy is the standard of care. Dependent from the tumor stage, adjuvant brachy- or teletherapy is recommended.
Rationale: Up to 5% of low-risk patients show occult lymph-node metastases, which can not be found by simple hysterectomy. On the other hand, node negative intermediate/high-risk patients do not profit from systematic lymphadenectomy. There is no proven survival benefit of adjuvant irradiation.
Study concept: Standardized observation and data acquisition of patients after surgery for endometrial cancer, including follow-up visits 6, 12 and 24 months after surgery as well as annual follow up from 24 months on. pre- and postoperative questionnaires concerning quality of life, lymph edema, bowel-, bladder- and sexual function.
Comparison of oncologic outcome as well as peri/postoperative morbidity between compartment based (PMMR) and conventional therapy.
PMMR is combined with Targeted compartmental lymphadenectomy (TCL):

Resection of the compartment including the first 2 draining nodes.

Organizational Data

- DRKS-ID: **DRKS00016541**
- Date of Registration in DRKS: **2019/07/01**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **17-7705-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- ICD10: **C54 - Malignant neoplasm of corpus uteri**

Interventions/Observational Groups

- Arm 1: **Therapy of endometrial cancer according to current guidelines follow-up visits 6, 12 and 24 months after surgery as well as annual follow up from 24 months on**
- Arm 2: **Therapy of endometrial cancer bei PMMR + TCL, followed by complete pelvic and paraaortic LNE in cases with positive nodes**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

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Assignment: **Parallel**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Progression-free Survival

Secondary Outcome

Overall Survival
QOL (EORTC QLQ-C30, SAQ, German Pelvic Floor Questionnaie, Lymphedema-Questionnaire).

Countries of recruitment

- DE **Germany**
- SE **Sweden**

Locations of Recruitment

- Medical Center **Universitätsklinikum Essen, Essen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/03/22**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Histologically proven endometrial carcinoma: endometroid and non-endometroid FIGO stages I-III; Karnofsky-Index ≥ 70; unrestricted operability; Age >=18 years.
- Completed treatment with according Cohort A, PMMR/targeted compartmental pelvic/paraaortic +/- complete pelvic and paraaortic LNE without adjuvant radiotherapy by the responsible clinic (clinician).
or
- Completed treatment according Cohort B, current clinical practice including adjuvant treatment based on ESMO/ESGO/ESTRO guidelines [26] by the responsible clinic (clinician).
- Informed consent of the patient

Exclusion criteria

Uterine pure sarcoma
- Distant metastases; sclerodermia, lupus erythematodes, mixed connective tissue disease; secondary malignancy; previous radiotherapy of the pelvis.
- Pregnancy
- Patients with diseases of the connective tissue will be excluded because of unforeseeable (e.g. neurological) symptoms and disorders after surgery.
- Postoperative radiotherapy could be administered with respect to the surgical field in R1 situation or if >= 5 lymph nodes were involved; in all other situations adjuvant radiotherapy will be an exclusion criterion for participation in the study cohort A.

Addresses

- **Primary Sponsor**

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  URL: **www.uniklinikum-essen.de**

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*