Endometrial Cancer Lymphadenectomy Trial (ECLAT)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

**Sponsor:**
Philipps University Marburg Medical Center

**Collaborator:**
German Cancer Aid

**Information provided by (Responsible Party):**
Philipps University Marburg Medical Center

**ClinicalTrials.gov Identifier:**
NCT03438474

**Recruitment Status:** Recruiting
**First Posted:** February 19, 2018
**Last Update Posted:** November 16, 2018

See [Contacts and Locations](https://clinicaltrials.gov/ct2/show/NCT03438474).

**Brief Summary:**
The primary aim of this trial is to ascertain whether or not systematic pelvic and para-aortic lymphadenectomy (LNE) does have a significant impact on overall survival (OS) in patients with endometrial cancer (EC) FIGO Stages
I or II and high risk of recurrence. Secondary aims will be to evaluate the effect of LNE on disease free survival (DFS) and quality of life, as well as the complications and side effects of LNE and the number of resected lymphnodes. 640 patients with histologically confirmed EC with high risk of recurrence (stage pT1b - pT2, all histological subtypes; pT1a, G3 endometrioid or serous or clear cell EC or carcinosarcomas) will be randomized. In Arm A, a total hysterectomy and bilateral salpingo-oophorectomy and in case of serous or clear cell EC additionally an omentectomy will be performed. In arm B in addition a systematic pelvic and para-aortic LNE up to the level of the left renal vein will be performed.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer of Endometrium Stage I</td>
<td>Procedure: Standard surgical procedure for endometrial cancer</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Cancer of Endometrium Stage II</td>
<td>Procedure: systematic lymphadenectomy (LNE)</td>
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</tbody>
</table>

**Study Design**

**Study Type**: Interventional (Clinical Trial)

**Estimated Enrollment**: 640 participants

**Allocation**: Randomized

**Intervention Model**: Parallel Assignment

**Masking**: None (Open Label)

**Primary Purpose**: Treatment

**Official Title**: Pelvic and Para-aortic Lymphadenectomy in Patients With Stage I or II Endometrial Cancer With High Risk of Recurrence

**Actual Study Start Date**: March 28, 2018

**Estimated Primary Completion Date**: February 15, 2028

**Estimated Study Completion Date**: February 15, 2029

**Arms and Interventions**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: Arm A standard surgical procedure</td>
<td>Procedure: Standard surgical procedure for endometrial cancer</td>
</tr>
<tr>
<td></td>
<td>total hysterectomy, bilateral salpingo-oophorectomy, omentectomy (type 2 cancers)</td>
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<tr>
<td></td>
<td>Standard surgical procedure for endometrial cancer:</td>
</tr>
<tr>
<td></td>
<td>total hysterectomy, bilateral salpingo-oophorectomy, omentectomy (type 2 cancers)</td>
</tr>
<tr>
<td>Experimental: Arm B systematic lymphadenectomy (LNE)</td>
<td>Procedure: Standard surgical procedure for endometrial cancer</td>
</tr>
<tr>
<td>In addition to standard procedures as defined for Arm A:</td>
<td>total hysterectomy, bilateral salpingo-oophorectomy, omentectomy (type 2 cancers)</td>
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</tbody>
</table>
Outcome Measures

**Primary Outcome Measures**: 
1. Overall survival (OS) [ Time Frame: 60 months ]
   Impact of systematic pelvic and para-aortic lymphadenectomy (LNE) on overall survival in EC patients with high risk of recurrence

**Secondary Outcome Measures**: 
1. Disease free survival (DFS) [ Time Frame: 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 21 months, 24 months, 27 months, 30 months, 33 months, 36 months, 42 months, 48 months, 54 months, 60 months ]
   Impact of systematic pelvic and para-aortic lymphadenectomy (LNE) on Disease free survival

2. Disease specific survival (DSS) [ Time Frame: 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 21 months, 24 months, 27 months, 30 months, 33 months, 36 months, 42 months, 48 months, 54 months, 60 months ]
   Impact of systematic pelvic and para-aortic lymphadenectomy (LNE) on Disease specific survival

3. Assessment of serious complications [ Time Frame: during surgery, at hospital discharge, day 60, 6 months, 9 months, 12 months ]
   Assessment of perioperative complications and site effects of LNE

4. EORTC QLQ-C30 [ Time Frame: Baseline, at hospital discharge, 6 months, 9 months, 12 months, 15 months, 18 months, 21 months, 24 months, 27 months, 30 months, 33 months, 36 months, 42 months, 48 months, 54 months, 60 months ]
   Health related Quality of life (QoL)

5. EORTC QLQ-EN24 [ Time Frame: Baseline, at hospital discharge, 6 months, 9 months, 12 months, 15 months, 18 months, 21 months, 24 months, 27 months, 30 months, 33 months, 36 months, 42 months, 48 months, 54 months, 60 months ]
   Health related Quality of life (QoL)
6. Number of resected lymph nodes [Time Frame: during surgery]

   resected pelvic and para-aortic lymph nodes

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Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](https://clinicaltrials.gov).

Ages Eligible for Study: 18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. histologically confirmed EC of clinical stages T1b and T2 (all histological types) and stage T1a G3 type 1 (endometrioid, endometrioid with squamous differentiation, mucinous) or type 2 tumors (any percentage of serous or clear cell component) or carcinosarcoma
2. a) no previous surgery concerning EC (primary surgery) or b) surgery after hysterectomy (e.g. for presumed low risk endometrial cancer) is allowed within 8 weeks after hysterectomy if no LNE was performed (secondary surgery)
3. absence of bulky lymph nodes
4. performance status ECOG 0-1
5. age 18 - 75 years
6. written informed consent
7. adequate compliance

Exclusion Criteria:

1. stage pT1a, G1 or G2 tumors of type 1 histology
2. sarcomas (except for carcinosarcoma = malignant mixed Müllerian tumor)
3. EC of FIGO stages III or IV (except for microscopical lymph node metastases)
4. evidence of extrauterine disease by visual inspection
5. recurrent EC
6. preceding chemo-, radio, or endocrine therapy for EC
7. any concomitant disease not allowing surgery including lymphadenectomy and/or chemotherapy
8. any medical history indicating excessive peri-operative risk
9. any current medication containing considerable surgical risk (e.g. bleeding: due to oral anticoagulating agents)
10. any known disorder or circumstances making participation in trial and follow-up questionable. Insufficient compliance is expected.
11. patients with second malignancies if disease or treatment might have an impact on the patient's prognosis
12. known HIV-infection or AIDS
13. simultaneous participation in other clinical trials if not permitted by the steering committee (translational or QoL studies not interfering with the objectives of ECLAT are allowed)

Contacts and Locations

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German Cancer Aid

Investigators
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More Information

Responsible Party: Philipps University Marburg Medical Center
ClinicalTrials.gov Identifier: NCT03438474 History of Changes
Other Study ID Numbers: AGO-OP.6 KKS 228
First Posted: February 19, 2018 Key Record Dates
Last Update Posted: November 16, 2018
Last Verified: January 2018

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Additional relevant MeSH terms:
Endometrial Neoplasms Neoplasms by Site
Uterine Neoplasms Neoplasms
Genital Neoplasms, Female Uterine Diseases