

# AGO-OP.6 / ECLAT



**Pelvic and Para-aortic Lymphadenectomy in Patients with Stage I or II Endometrial Cancer with High Risk of Recurrence**

**Endometrial Cancer Lymphadenectomy Trial  
(ECLAT)**

**A Multicenter, Prospective Randomized Controlled Trial**

**Coordinating Investigators**  
Prof. Dr. med. Günter Emons  
PD Dr. med. Philipp Harter

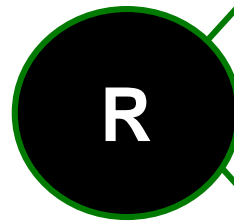


# *ECLAT-Endometrial Cancer Lymphadenectomy Trial*

AGO-OP.6



- histologically confirmed endometrial cancer
- FIGO IB, II (all subtypes)
- FIGO IA, G3 (type I)
- FIGO IA (Type II)
- Absence of bulky nodes
- Age 18-80y



n=640

## **System. lymphadenectomy**

- pelvic
- para-aortic

## **no lymphadenectomy**

**Primary endpoint: Overall Survival**

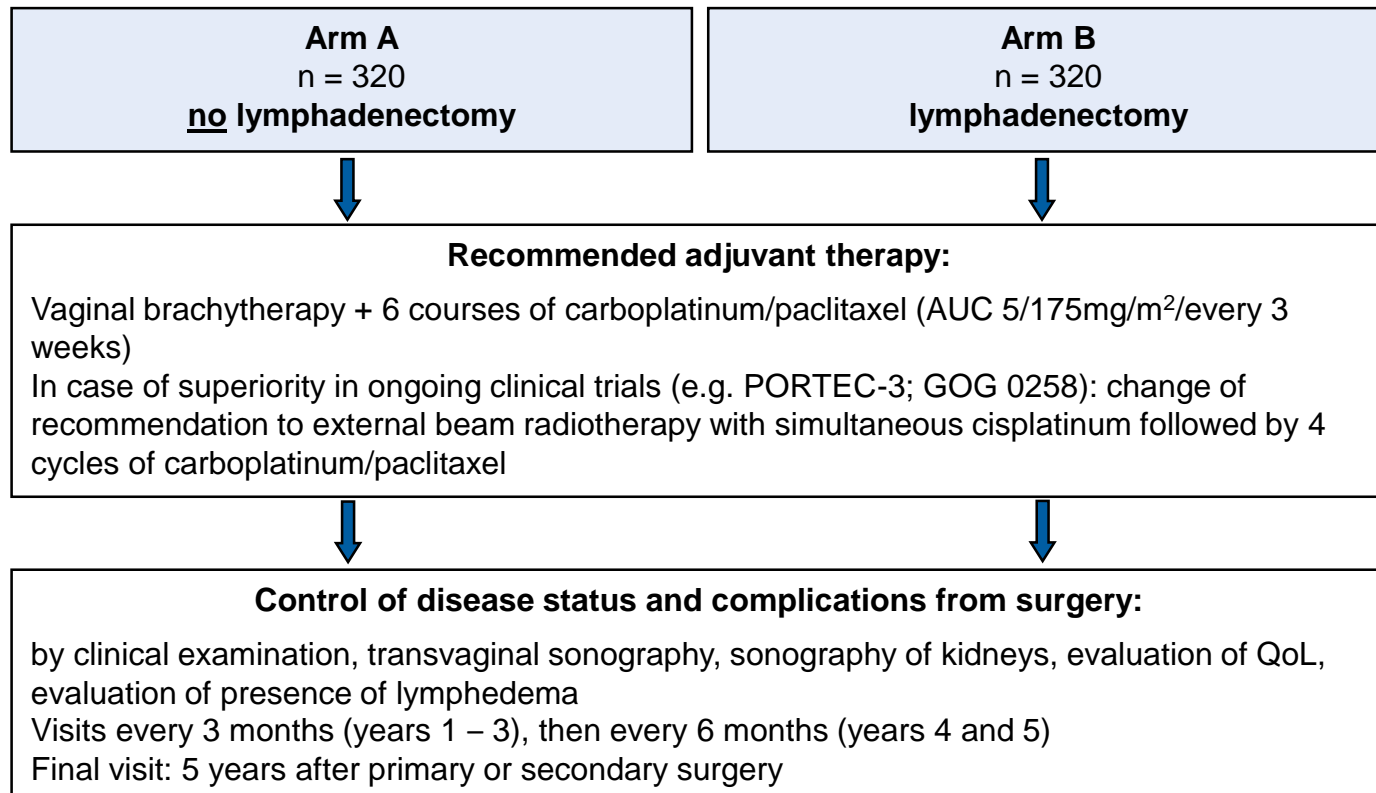
Type I: endometrioid, endometrioid + squamous differentiation, mucinous

Type II: serous, clear cell, carcinosarcoma

*SLN in LNE arm as additional procedure allowed*

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- **Primary endpoint:** Overall Survival (5 year OS 75 → 83%)
- **Secondary endpoints**
  - Disease free survival (DFS)
  - Disease specific survival (DSS)
  - Assessment of perioperative complications and site effects of LNE, lymph edema, lymph cysts
  - Health related Quality of life (EORTC QLQ-C30, EORTC QLQ-EN24)
  - Number of resected lymph nodes
- **Two ancillary projects**
  - Subproject FRAILTY
  - Subproject SLN



### Subproject FRAILTY

- The aim of the Subproject FRAILTY is to investigate if the exploration of frailty could be a conceptual method of quantifying a patient's fitness for surgery which might have a prognostic potential for surgical outcomes in patients who are undergoing oncological surgery

### Subproject SLN

- The aim of the Subproject SLN is to investigate the technique of identification, the number of identified SLN including the region compared to the results of the subsequent full LNE.



## Interested Groups

GINECO

NSGO

...

Participating centers have to qualify!

- Comparable to LION: 12 anonymous surgical and pathological reports of a systematic pelvic and para-aortic LNE at a high quality level within 12 months
- Active sites in LION without major changes in the surgical team: modified qualification process

# *ECLAT-Endometrial Cancer Lymphadenectomy Trial*

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- Randomized Phase III trial, prospective, multicenter
- Coordinating investigator: Günter Emons
- Sponsor: Philipps-University Marburg / AGO Study Group
- Planned number of patients: 640 pts. in 5 years
- Current accrual: not started yet
- Application to German Ethics Committee: July 2017
- So far, 40 German sites have qualified for participation.