GERMAN-FUNDED LAPAROSCOPIC APPROACH TO CERVICAL CANCER (G-LACC)

A Randomized Clinical Trial for Early-Stage Cervical Cancer

STUDY POPULATION

Inclusion criteria

- Primary adenocarcinoma, squamous cell carcinoma or adenosquamous carcinoma of the uterine cervix
- FIGO stage IA2, IB1 or IB2 disease (< 4 cm)
- Patients undergoing radical hysterectomy according either to Type II or III (Piver Classification) or to Type B or C (Querleu and Morrow classification) or TMMR procedure.

  Simple hysterectomy (SH) can be considered for patients with low-risk early-stage cervical cancer (SHAPE criteria: tumor < 2 cm, < 10 mm depth of stromal invasion on LEEP/cone). [1]

  SH has to be performed as extrafascial hysterectomy and the preaparation of a max. 5 mm vaginal cuff is required.
- Performance status of ECOG 0–1

Exclusion criteria

- Tumor size 4 cm and greater
- FIGO stage IB3 – IV
- Patients with a history of pelvic or abdominal radiotherapy
- Patients who are pregnant
- Patients with evidence of metastatic disease by conventional imaging studies, enlarged pelvic or aortic lymph nodes > 2 cm, or histologically positive lymph nodes
- Unfit for surgery, serious concomitant systemic disorders incompatible with the study

[1] Plante M, Kwon JS, Ferguson S, et al. Simple versus Radical Hysterectomy in Women with Low-Risk Cervical Cancer. N Engl J Med. 2024;390(9):819-829. doi:10.1056/NEJMoa2308900

[2] Park KJ, Selinger CI, Alvarado-Cabrero I, et al. Dataset for the Reporting of Carcinoma of the Cervix: Recommendations From the International Collaboration on Cancer Reporting (ICCR). Int J Gynecol Pathol. 2022;41(Suppl 1):S64-S89. doi:10.1097/PGP.0000000000000909

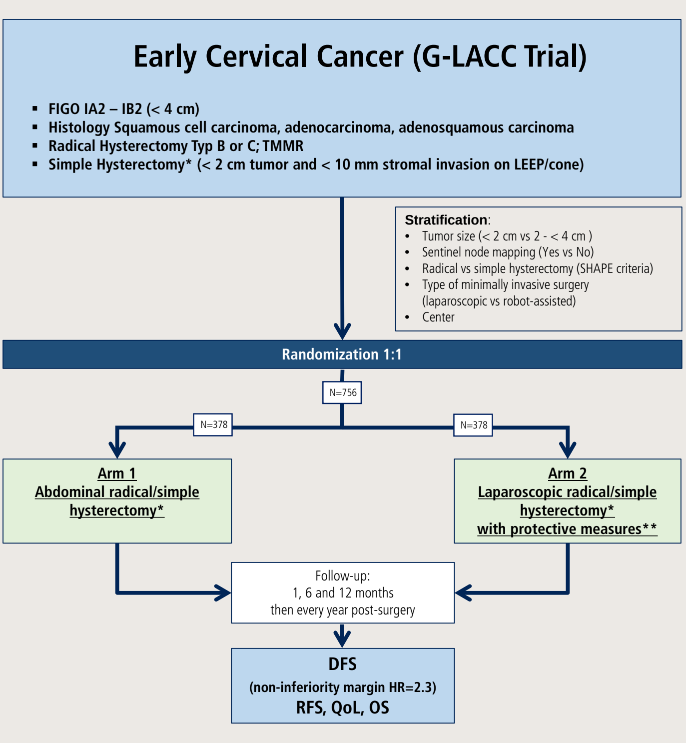

Fig. 1: Study schema of the G-LACC trial. DFS, disease-free survival; HR, hazard ratio; RFS, recurrence-free survival; QOL, quality of life; OS, overall survival; SLN, sentinel lymph node.

Surgery includes pelvic lymph node dissection or optional sentinel lymph node biopsy (SNB) according to current guidelines

*1 Simple hysterectomy can be considered for patients with low-risk early-stage cervical cancer (SHAPE-criteria: tumor < 2 cm and < 10 mm depth of stromal invasion (LEEP/cone) BUT has to be determined BEFORE randomization. In case of simple hysterectomy, extrafascial hysterectomy with max. 5mm vaginal cuff is required to ensure negative margins. [1]

*2 Tumor size assessment: the measurement in any prior specimens (loop / cone excision) has to be taken into account. It is recommended to add together the measurements in different specimens. **Tumor size = loop/cone specimen + surgical specimen.** [2]

** Protective measures: LEEP/conisation before randomization or closure of the vagina before colpotomy. Transcervical manipulators are not permitted. Use of uterus manipulators / cervical adapter (without transcervical device) are allowed only after LEEP/conization.

Investigational treatment

Laparoscopic or robot-assisted radical or, in case of SHAPE criteria, simple hysterectomy

Control treatment

Abdominal radical or, in case of SHAPE criteria, simple hysterectomy

Study duration

Recruitment: 48 months
Follow-up: 60 months (5 years)
Duration of the entire trial: 108 months

STUDY SYNOPSIS

Study design

Interventional, multicenter, open-label, randomized, controlled non-inferiority trial.

Subject population

Female patients with operable early- stage cervical cancer:

- FIGO stage IA2 - IB2
- < 4 cm
- Histologic subtype of squamous-cell carcinoma, adenocarcinoma, or adenosquamous carcinoma

Objectives

Primary Objective:

To investigate the oncologic safety of laparoscopic or robot-assisted radical / simple hysterectomy (LRH) compared to abdominal radical / simple hysterectomy (ARH) using pre-specified surgical techniques and qualitative standards and to demonstrate the non-inferiority of LRH compared to ARH with a non-inferiority margin of 2.3 for the hazard ratio (HR) for disease free survival (DFS), defined as the time from randomization to disease recurrence or death from any cause (whichever occurs first).

Secondary Objective:

To evaluate overall survival, disease recurrence, quality of life, complications and treatment-associated morbidity, treatment costs and cost effectiveness.

CONTACT INFORMATION

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JOIN G-LACC TRIAL

Dear Investigator,

Thank you for being interested in participating in the G-LACC trial. In order to evaluate your site for participation, we kindly ask you to provide the following information:

- Specialization in Gynecologic Oncology
- 5 anonymized surgical reports of open abdominal radical hysterectomy +/- LNE
- 5 anonymized surgical reports of laparoscopic or robot-assisted radical hysterectomy +/- LNE
- Accompanied by corresponding anonymized pathological report
- Declaration of commitment

Please send the documents to the following address:

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