## Trial Description

### Title

**Prospective, randomized and multicenter study for investigation of validity of the sentinel lymph node concept in patients with cervical cancer ≤ 2 cm**

### Trial Acronym

**SENCER**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**Aim of the present study is to show, if only removal of sentinel lymph nodes in women with early cervical
cancer leads to an equal overall survival compared to systematic radical pelvic lymphadenectomy and at
the same time is accompanied with considerable reduction of intra- and post operative complications.**

### Brief Summary in Scientific Language

**Aim of the present study is to show, if only removal of sentinel lymph nodes in women with early cervical
cancer leads to an equal overall survival compared to systematic radical pelvic lymphadenectomy and at
the same time is accompanied with considerable reduction of intra- and post operative complications.
We plan to randomize 1200 patients with histologically confirmed cervical cancer stage FIGO 1a1 L1 V0,
FIGO 1a2 L0 or L1 V0, FIGO1b1 L0 or L1 V0 ≤ 2 cm. In group A exclusively sentinel lymphadenectomy is
performed, in group B radical systematic pelvic lymphadenectomy is done. All the patients from both groups with tumor free
lymph nodes either radical hysterectomy or, in women seeking parenthood, radical trachelectomy is
performed. In all patients, if lymph nodes are tumor-involved systematic pelvic and paraaortic lymphadenectomy
followed by primary chemoradiation is recommended.
Primary end point is overall survival which should be equal for both groups. Secondary end point is periand
postoperative morbidity including quality of life, where a benefit for women with sentinellymphadenectomy
should be evident.**

### Do you plan to share individual participant data with other researchers?

**Do you plan to share individual participant data with other researchers?**

**[---]***

**Description IPD sharing plan**

**[---]***

## Organizational Data

- DRKS-ID: **DRKS00003164**
- Date of Registration in DRKS: **2011/07/05**
- 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.: **EA1/207/09 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

## Secondary IDs

## Health condition or Problem studied

- Free text: **cervical cancer**
- ICD10: **C53.9 - Malignant neoplasm: Cervix uteri, unspecified**

## Interventions/Observational Groups

- Arm 1: **sentinel lymphadenectomy**
- Arm 2: **radical pelvic lymphadenectomy**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Single blind**
- Who is blinded: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **Single blind**

Who is blinded: **[---]***

- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

### Primary Outcome

**Overall survival**

### Secondary Outcome

**Peri- and postoperative morbidity**
**Quality of life judged trough questionnaire EORTC QLQ C-30 (3 months after operation, then yearly till 4 year follow-up)**
**Recurrence-free survival**

## Countries of recruitment

- DE **Germany**
- PL **Poland**

## Locations of Recruitment

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2011/09/01**
- Target Sample Size: **1200**
- Monocenter/Multicenter trial: **Multicenter trial**
-

Planned/Actual: **Planned**

(Anticipated or Actual) Date of First Enrollment: **2011/09/01**

Target Sample Size: **1200**

Monocenter/Multicenter trial: **Multicenter trial**

National/International: **International**

### Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

### Additional Inclusion Criteria

**- Karnofsky-Index =/> 70,**
**- 18-80 year of age**
**- Cervical cancer diagnosed histologically**
**- FIGO 1a1 L1 V0, FIGO 1a2 L0 or L1 V0 FIGO 1b1 L0 or L1 V0 ≤ 2cm**
**- Signed informed consent form**
**- Patient's willing to cooperate**

### Exclusion criteria

**- Neuroendocrine tumours or tumours of mixed type with neuroendocrine component**
**- Invasion of tumour cells in vascular system (V1)**
**- Pregnancy, breast feeding**
**- Distant metastases**
**- Previous malignant diseases**
**- History of pelvic radiotherapy**
**- Severe medical disorders**
**- Psychiatric diseases, that can interfere with participation and follow-up**
**- HIV infection or AIDS**
**- Drugs addiction**
**- Existing motoric or sensoric polyneuropathy > CTC Grad 1**
**- impossibility to perform anesthesia**

## Addresses

- **Primary Sponsor**

**Charité Campus Charité Mitte**
**Charitéplatz 1**

**Primary Sponsor**

**Charité Campus Charité Mitte**
**Charitéplatz 1**
**10117 Berlin**
**Germany**

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■ **Contact for Scientific Queries**

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## Sources of Monetary or Material Support

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

**Charité Campus Charité Mitte**
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**Germany**

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## Status

- Recruitment Status: **Recruiting planned**
- 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.*