Deutsches Register Klinischer Studien
German Clinical Trials Register

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

# Trial Description

## Title

**Prospective trial for evaluation of potential heart dose reduction using deep inspiration breath-hold in radiotherapy of left-sided breast cancer**

## Trial Acronym

**[---]***

## URL of the trial

**[---]***

## Brief Summary in Lay Language

**Objective of the study is to evaluate how the heart dose during radiotherapy with surface surveillance of left-sided breast cancer can be significantly reduced by a gated radiotherapy in deep inspration and in a second step to check how a radiotherapy in deep inspiration breath-hold can be implemented and monitored in clinical routine.**

## Brief Summary in Scientific Language

**Objective of the study is to evaluate how the heart dose during radiotherapy of left-sided breast cancer can be significantly reduced by a gated radiotherapy (gated deep inspiration breath-hold with audio-visual feedback) in deep inspration and in a second step to check how a radiotherapy in deep inspiration breath-hold can be implemented and monitored in clinical routine. For gated treatment a surface-scanner and individual audio-visual feedback with loudspeaker announcements and video glasses were used.**

# Organizational Data

- DRKS-ID: **DRKS00010929**
- Date of Registration in DRKS: **2016/08/05**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **496-12 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

# Secondary IDs

## Health condition or Problem studied

- ICD10: **C50.9 - Malignant neoplasm: Breast, unspecified**

## Interventions/Observational Groups

- Arm 1: **Irradiation and Planning in deep inspiration breath-hold for left sided breast cancer patients using the sentinelTM/catalystTM surface System and automatic interconnection for beam-on/-off Signal via ELEKTA Response II TM Interface. For Treatment planning the oncentra 4.3 Software was used.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

**significant heart dose reduction in planning and Treatment checked by heart inside Treatment field and further Parameters like heart mean and max dose as well as max LAD (left anterior descending artery) dose.**

### Secondary Outcome

**lung dose assessment (mean lung dose, left lung V20Gy), target dose coverage (V95%), clinical feasability**

**Follow-Up using Lent-Soma Criteria**

**Follow-Up for cardiac toxicity (10-20 years) no endpoint of this study**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Medical Center **Klinikum Großhadern - Klinik für Strahlentherapie und Radioonkologie, München**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/11/01**
- Target Sample Size: **13**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

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

### Additional Inclusion Criteria

**left-sided breast cancer**
**indication for adjuvant whole breast irradiation**

### Exclusion criteria

**informed consent not possible**
**breath-hold of 20 seconds not possible**

## Addresses

- **Primary Sponsor**

  **C-RAD AB**
  **75320 Uppsala**
  **Sweden**

  Telephone: **[---]***
  Fax: **[---]***

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- **Contact for Scientific Queries**

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- **Contact for Public Queries**

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## Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**ELEKTA AB**
**10393 Stockholm**
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**Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/12/31**

## Trial Publications, Results and other documents

- Paper **Open Acces Zugriff**

* *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.*