IORT-Boost-Study, Prospective Observational Study for Intraoperative Radiotherapy of the Breast as a Boost

NCT-Nummer:
NCT02114086

Studienbeginn:
Januar 2013

Letztes Update:
04.03.2021

Wirkstoff:
-

Geschlecht:
Frauen

Altersgruppe:
Alle

Phase:
-

Sponsor:
Kantonsspital Münsterlingen

Collaborator:
-

Studien-Informationen

Brief Summary:

In this study the investigators observe the investigation, whether the new method for Boost-Irradiation with the Intrabeam Device of Zeiss Germany influences local recurrence, acute and late effects of Radiotherapy, overall survival, quality of life and cosmesis.

Ein-/Ausschlusskriterien

Inclusion Criteria:

- women with histologically proven unifocal ductal-invasive or other histology of

breast-cancer, size of tumor < or = 3.5 cm

- written informed consent

- ability to cooperate

- full legal capability

Exclusion Criteria:

- missing written informed consent

- lack of compliance

Studien-Rationale

Primary outcome:

1. number of Participants with local recurrence histologically proven (Time Frame - up to 10 years):
Recurrence of breast cancer proven by histology

Secondary outcome:

1. observation of acute and late effects of Radiotherapy (Time Frame - up to 10 years):
acute effects of Radiotherapy are assessed by Common Toxicity Criteria for Adverse Effects (CTCAE Version 4.0) and late effects of Radiotherapy are assessed by Late Effects Normal Tissue Subjective Objective Management Analysis (LENT-SOMA)

2. Overall survival (Time Frame - up to 10 years):
The number of Patients who died is assessed.

3. Quality of life (Time Frame - up to 10 years):
Quality of life is assessed by European Organization for Research and Treatment of Cancer (EORTC) quality of life questionnaires (QLQ) cancer modul (C30) EORTC-QLQ-C30 version 3.0 and breast cancer modul (BR23) EORTC-QLQ-BR23

4. Cosmesis (Time Frame - up to 10 years):
Cosmesis is assessed by Photographs and evaluated automatically.

Studienleiter

Christiane Reuter, Dr. med.
Study Director
Kantonsspital Münsterlingen

Studienlocations (1 von 1)

KMünsterlingen
8596 Münsterlingen
Switzerland

Quelle: ClinicalTrials.gov