LIMBURGS ONCOLOGISCH CENTRUM V Z W

jessa ZIEKENHUIS

SPYCRA PROTECT ®

Study project

Evaluation of Spycra Protect® for the prevention of radiodermatitis (RD)

Study Design

Background

Acute radiodermatitis (ARD) :

- Skin reactions occurring as a consequence of ionizing radiation
- Affects up to 95% of the patients undergoing external beam radiotherapy (RT)
- Compromises patients' quality of life (painful and distressing)
- Might jeopardize treatment outcomes when evolving towards more severe forms (leading to treatment interruption/ discontinuation)

Objective

To assess the efficacy, practicability, and cost-effectiveness of Spycra Protect® in preventing RD in breast cancer patients

Population

Eligibility Assessment for all women scheduled for radiotherapy simulation for breast tumor at Jessa Ziekenhuis

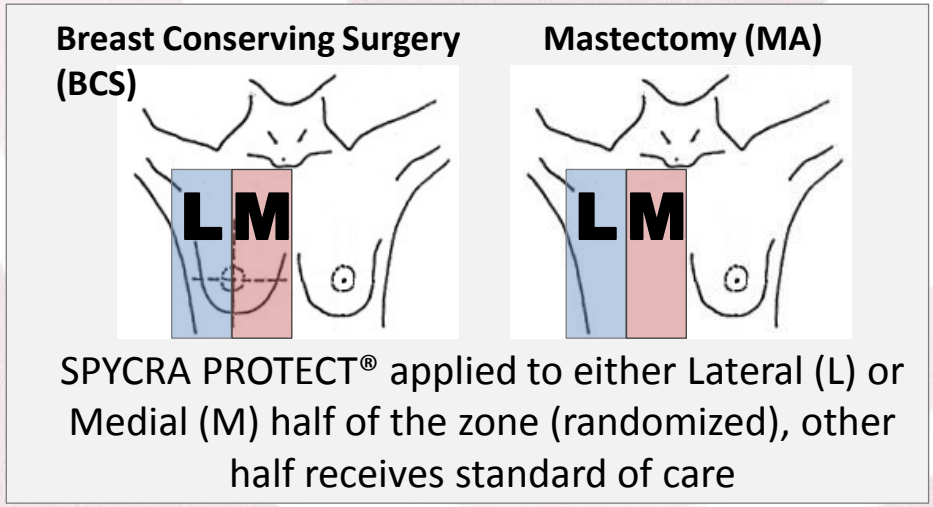
Inclusion Criteria	Exclusion Criteria
✓ Post-surgery (lumpectomy OR mastectomy) ✓ Scheduled for hypofractionated radiotherapy (resp. 16*2.5Gy + 5*2.5Gy OR 16*2.5Gy) at Jessa ✓ Medium to large breast size[a] ✓ Be able to fill out questionnaire autonomously ✓ Signed informed consent	✓ Metastatic disease ✓ Concurrent chemotherapy ✓ Previous irradiation to the same breast ✓ Brachy therapy ✓ Infection of the to-be-irradiated zone ✓ Bolus

[a] Since breast size is a critical risk factor for RD, only medium-to-large-breasted women will be included in the study.

Design

- **Randomized intra-patient controlled study**:

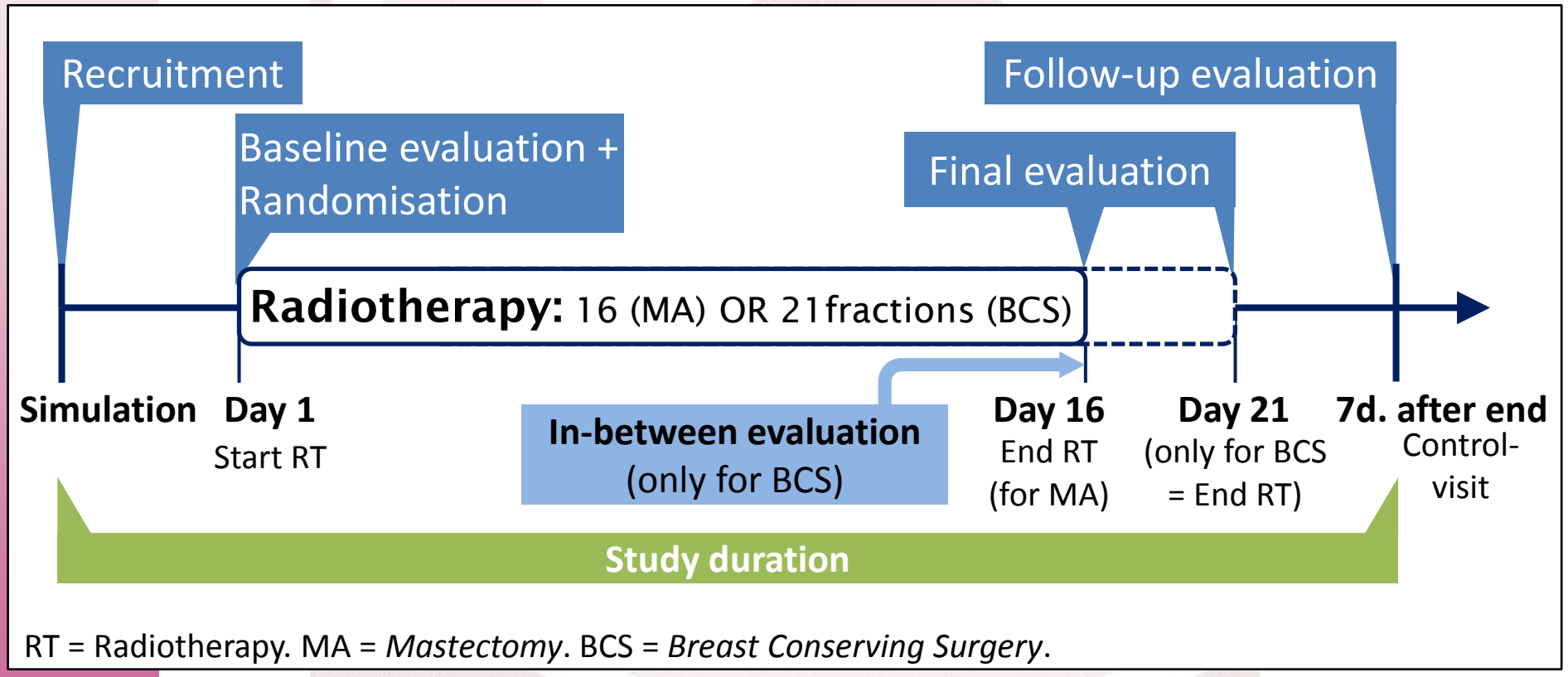
  For each patient: the to-be-irradiated zone (breast or chest wall) will be divided into two symmetrical halves (medial and lateral halves) for randomization to either standard skin care or Spycra Protect®.



SPYCRA PROTECT® applied to either Lateral (L) or Medial (M) half of the zone (randomized), other half receives standard of care

Design

➢ **Procedure**:



RT = Radiotherapy. MA = *Mastectomy*. BCS = *Breast Conserving Surgery*.

Design

- **Randomization**:
  - ✓ Based on pre-prepared, computer-generated scheme (using permuted block randomisation)
  - ✓ Conducted by the co-PI who has no patient involvement at all
  - ✓ Stratified by surgery type (mastectomy vs lumpectomy) and, within lumpectomy, by breast size (medium and large size, as defined by the RTOG 97-13 trial[1] criteria)

NB: Blinding of treatment allocation (= allocation concealment) will be ensured

[1] Fisher et al. Int J Radiat Oncol Biol Phys 2000;48:1307-1310.

Design

- **Sample size**:
  - ✓ No previous study with Spycra protect
  - ✓ Study using silicone dressing[2] considered a 28% decrease as clinically significant
  - ✓ Power analysis[3]: Sample size of 61 would detect a 30% decrease with 80% power (with alpha-level of 0.05).

=> In order to account for attrition, we intend to **recruit 80 participants**

[2] Paterson et al. J Cancer Sci Ther 2012;4:347-356. [3] Based on an online a priori sample size calculator, with % of moist desquamation in previous study as standard: https://www.dssresearch.com/KnowledgeCenter/toolkitcalculators/samplesizecalculators.aspx

Design

- **Timepoints**:
  - ✓ T0: Fraction 1 of RT (baseline at start RT)
  - ✓ T1: Fraction 16 (only for patients having had breast-conserving surgery)
  - ✓ T2: End of RT: Fraction 16 for mastectomy or fraction 21 for breast-conserving surgery
  - ✓ T3: 1 week (7d) follow-up

Design

- **Endpoints**:

1. ARD severity (RTOG grades)

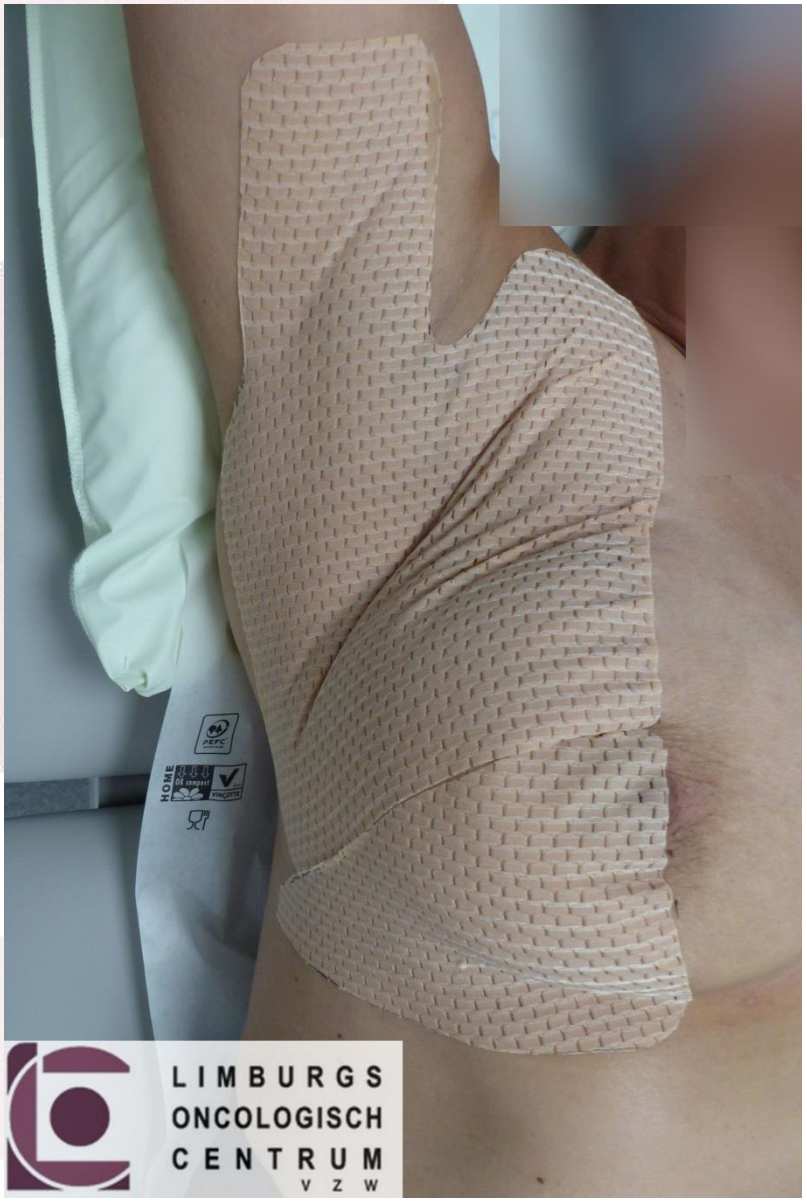
- ✓ Objective: by RT-nurses & by independent, blinded raters (based on photos, 0-10 Numerical Rating Scales)
- ✓ Subjective: by patients (0-10 Numerical Rating Scales)

2. Product evaluation:

- ✓ By nurses (easiness of use, cost-effectiveness, satisfaction)
- ✓ By patients (pleasantness, soothing effect, global satisfaction)

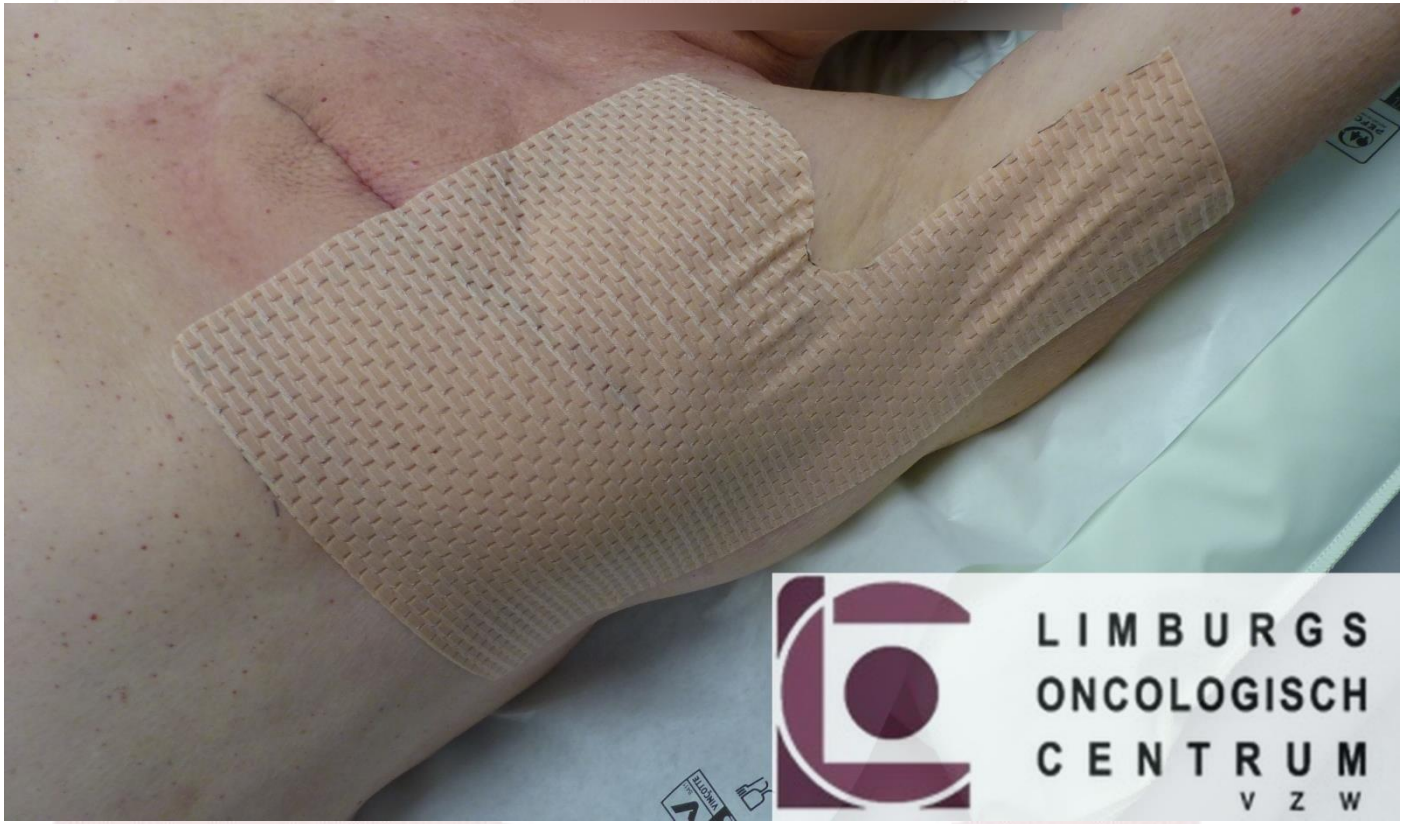
Examples

Example of Spycra Protect ® applied on the lateral side of the breast



Example

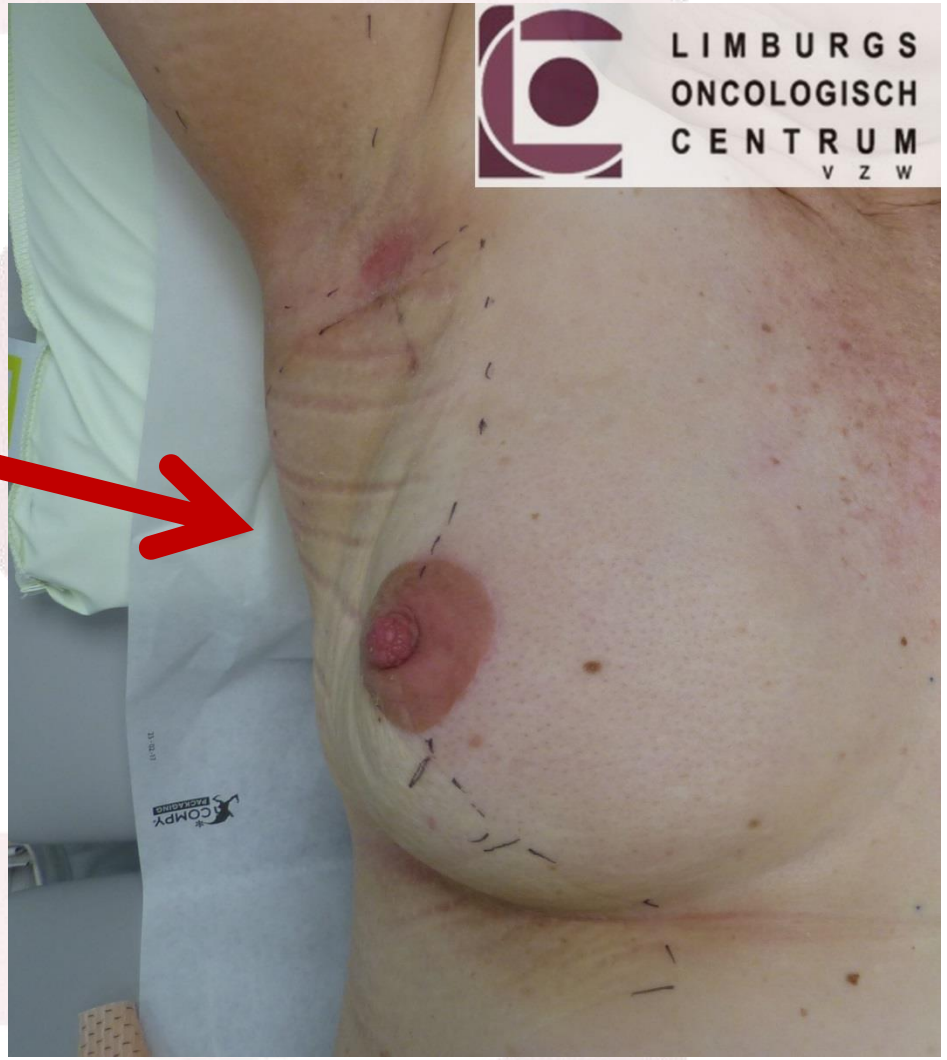
Example of Spycra Protect ® applied on the lateral side of the chest wall



Example

End of radiotherapy, lateral half received SPYCRA PROTECT®

(clearly reduced erythema)



Example

Patient received SPYCRA PROTECT® preventively from the start of RT. At the end of RT: