

**DBCg – SKAGEN TRIAL 1**

DANISH BREAST CANCER COOPERATIVE GROUP

**INCLUSION FORM**

Loco-regional RT 50 Gy versus 40 Gy

Name – patient ID   <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> -            <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> -            <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> -            <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: small; margin-top: 2px;"> <span>Day</span> <span>Month</span> <span>year</span> <span>No.</span> </div>	Hospital, department
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**Instructions:** This form should be completed before inclusion in the protocol. Only if all the boxes of the selected column is ticked, the patient is suitable for treatment according to the protocol.

The form is available on DBCg's website ( [www.dbcg.dk](http://www.dbcg.dk) ).

Choose the Web entry menu, enter Username and Password, follow the instructions as described.

**Inclusion criteria:**

Histologically proven invasive breast carcinoma pT1-3, pN0-N3, M0 or operated after primary systemic therapy for inv. breast carcinoma ypT0-3, ypN0-3, M0	<input type="checkbox"/> yes	<input type="checkbox"/> no
Candidate for regional nodes RT without nodal boost	<input type="checkbox"/> yes	<input type="checkbox"/> no
Woman aged ≥ 18 years	<input type="checkbox"/> yes	<input type="checkbox"/> no
WHO performance 0-2	<input type="checkbox"/> yes	<input type="checkbox"/> no
Randomisation within 42 days after last surgery or within 4 weeks after last chemotherapy	<input type="checkbox"/> yes	<input type="checkbox"/> no
Capable of completing therapy, planned follow up visits and investigations	<input type="checkbox"/> yes	<input type="checkbox"/> no
Fertile women: uses contraception if relevant	<input type="checkbox"/> yes	<input type="checkbox"/> no
Charlsons morbidity form and pathology form are available	<input type="checkbox"/> yes	<input type="checkbox"/> no
Informed approval to trial (signed patient folder):	<input type="checkbox"/> yes	<input type="checkbox"/> no

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**Exclusion criteria:**

Bilateral breast carcinoma	<input type="checkbox"/> no	<input type="checkbox"/> yes
Previous RT to breast / thorax	<input type="checkbox"/> no	<input type="checkbox"/> yes
Concurrent / previous malignancy which may influence therapy or follow up	<input type="checkbox"/> no	<input type="checkbox"/> yes
Pregnant or lactating	<input type="checkbox"/> no	<input type="checkbox"/> yes
Surgery	<input type="checkbox"/> Mastectomy <input type="checkbox"/> Lumpectomy	
Systemic therapy	<input type="checkbox"/> Endocrine or no systemic therapy <input type="checkbox"/> Chemotherapy (incl. endocrine / trastuzumab)	
Boost	<input type="checkbox"/> no	<input type="checkbox"/> yes
Connective tissue disease If yes; diagnosis _____	<input type="checkbox"/> no	<input type="checkbox"/> yes

**Filled by DBCG**

Randomization no. 

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Result of randomization :

Regime 1 (Radiotherapy 40 Gy / 15 fr)

Regime 2 (Radiotherapy 50 Gy / 25 fr)

Date 

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 ddmmyy

**Form filled in by:**

Name: \_\_\_\_\_  
(CAPITAL LETTERS)

Sign.: \_\_\_\_\_

Date 

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