

DBCG 2018 RT Natural trial**INCLUSION SCHEME**

Partial breast radiation therapy versus no radiation therapy

Patient name and birth day.	Hospital.
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Guide: This scheme must be filled in before randomization in the trial. Randomization is only possible when all items are answered.

The scheme is available on the DBCG webpage (www.dbcg.dk).

Inclusion criteria:

Histological invasive breast cancer pT1, pN0, M0	<input type="checkbox"/> yes	<input type="checkbox"/> no												
Resection margin ≥ 2 mm after lumpectomy. The patient is a candidate for partial breast irradiation	<input type="checkbox"/> yes	<input type="checkbox"/> no												
Woman of age ≥ 60 years	<input type="checkbox"/> yes	<input type="checkbox"/> no												
Adenocarcinoma ≤ 20 mm, non-lobular, unilateral and unifocal	<input type="checkbox"/> yes	<input type="checkbox"/> no												
Tumour malignancy grade I or II, estrogen receptor positive $\geq 10\%$, HER2 status negative	<input type="checkbox"/> yes	<input type="checkbox"/> no												
WHO performance 0-2	<input type="checkbox"/> yes	<input type="checkbox"/> no												
Randomization within 42 days from last surgery (lumpectomy, reexcision, axillary surgery)	<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												
Charlsons morbidity form and pathology form are available	<input type="checkbox"/> yes	<input type="checkbox"/> no												
Informed approval to trial (signed patient folder):	<table border="1" style="display: inline-table; text-align: center;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td>dd</td> <td>mm</td> <td>yy</td> <td></td> <td></td> <td></td> </tr> </table>								dd	mm	yy			
dd	mm	yy												

Exclusion criteria:

Previous RT to breast / thorax	<input type="checkbox"/> no	<input type="checkbox"/> yes
Concurrent / previous malignancy or skin diseases which may influence therapy or follow up	<input type="checkbox"/> no	<input type="checkbox"/> yes

Systemic therapy (must be filled in)	<input type="checkbox"/> no systemic therapy
	<input type="checkbox"/> systemic therapy

Filled in by DBCG

Randomization number.

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Randomized to:

Regiment 1 (partial breast RT 40 Gy / 15 fr)

Regiment 2 (no RT)

Date

 ddmmyy

Scheme filled in by:

Name: _____
(Capital letters)

Sign.: _____

Date

 ddmmyy