

# Long-term outcomes and predictive factors for survival in premenopausal breast cancer treated with tamoxifen

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<b>Registration date</b> 06/12/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/02/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Breast cancer accounts for 1/3 of all malignant diagnosis among females world-wide and is often detected in an early stage. The 5-years survival of breast cancer is about 90%, both due to early screening detection and adjuvant therapy. Despite this, breast cancers might develop recurrence throughout the 20 years after diagnosis. For premenopausal women, breast cancer is a leading cause of death and patients are still being under- and over-treated due to imperfect models to predict outcomes. The possibility to de-escalate therapy, without detrimental effect on survival, is warranted. A majority of breast cancer tumours are sensitive to endocrine treatment, and the patients are generally recommended adjuvant endocrine therapy alone or with additional chemotherapy. Tamoxifen is the most recommended oral drug as adjuvant endocrine therapy in premenopausal women.

This study aims to analyse tissue samples taken during an earlier trial and relate their characteristics to the long-term outcomes in the patients who took part in the earlier trial

### Who can participate?

Participants from the earlier SBI:2 trial (1986-1991)

### What does the study involve?

Tissue samples collected during the original SBI:2 trial will be analysed and their characteristics compared to the long-term outcomes of the patients

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

Skåne University Hospital, Sweden

### When is the study starting and how long is it expected to run for?

May 2018 to December 2024

Who is funding the study?  
Governmental funding for clinical research within the Health Care Sector

Who is the main contact?  
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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

SBI:2 BioLong (1)

# Study information

## Scientific Title

Premenopausal patients randomized to adjuvant tamoxifen versus not: long-term survival in relation to genomic and tumor related factors

## Acronym

SBI:2 BioLong

## Study objectives

Comprehensive genomic and histopathological characterization of primary tumours can improve prediction of long-term prognosis and tamoxifen response in premenopausal patients

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 02/02/2017 Lund ethics committee (Box 133, 221 00, Lund; +46 2224180; eva.elvstrand@epn.lu.se), ref: 2015/6
2. Approval for long-term follow-up (Dnr number LU 2015/350) and genomic analyses (Dnr LU 2017/97)

## Study design

Prospective-retrospective multicentre interventional randomized trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Premenopausal patients with invasive breast cancer

## Interventions

The SBI:2 BioLong study is based on a prospective multicenter randomized clinical trial with > 30 years of follow-up of adjuvant tamoxifen

We will collect formalin-fixed archival tissue for gross evaluation of tumour-infiltrating lymphocytes, characterization of them and assessment of lymphovascular invasion in relation to the primary outcome. RNA and DNA will be extracted to enable RNA profiling by PAM50 and additional gene expression analysis with the 360TM panel. Mutational analysis is scheduled to include ESR1, p53, FGFR and PI3K to identify mutations of importance for tamoxifen resistance. The PAM50 and Risk of Recurrence has been thoroughly evaluated on tumors from postmenopausal patients allocated to hormonal therapy and provides additional prognostic information to conventional prognostic markers. Data on prognosis by PAM50 for premenopausal women is sparse and restricted to less than 10 years of follow up. Surrogate subtyping will additionally be compared to the intrinsic subtypes in terms of prognostic capacity

The original SBl:2 trial (1986-1991) is unique as its inclusion was restricted to premenopausal patients and the control arm includes patients without any systemic therapy, the intervention arm received two years of therapy with tamoxifen. The 30 years of follow-up regarding breast cancer mortality, breast cancer-free interval (BCFi) and distant recurrence-free interval (D-RFi) has been published. The SBl:2 BioLong study will add important genomic and histopathological data to improve our knowledge on factors of importance for long-term prognosis in premenopausal patients.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Tamoxifen

### **Primary outcome(s)**

BCFi (Breast cancer free interval) over the ~30-year period, measured using patient notes

### **Key secondary outcome(s)**

1. D-RFi (Distant Recurrence Free interval) over the ~30-year period, measured using patient notes
2. Breast cancer mortality over the ~30-year period, measured using patient notes
3. Overall mortality over the ~30-year period, measured using patient notes

### **Completion date**

31/12/2024

## **Eligibility**

### **Key inclusion criteria**

Patients radically operated for invasive breast cancer stage II in the SBl:2 trial

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

564

**Key exclusion criteria**

1. Postmenopausal status
2. Metastatic disease

**Date of first enrolment**

01/05/2018

**Date of final enrolment**

31/12/2024

## **Locations**

**Countries of recruitment**

Sweden

**Study participating centre**

Skåne University Hospital

Box 177

Lund

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## **Sponsor information**

**Organisation**

Lund University

**ROR**

<https://ror.org/012a77v79>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Governmental funding for clinical research within the Health Care Sector

**Funder Name**

Fre Bertha Kamprad Foundation

**Funder Name**

Anna och Edwin Bergers Foundation

**Funder Name**

Gyllenstiernska Krapperup Foundation

**Funder Name**

Futurum—the Academy for Health and Care

**Funder Name**

The Clinical Cancer Research Foundation in Jönköping

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Interim results article</a>	Results on predictive value of tumour-infiltrating lymphocytes	23/12/2020	29/12/2020	Yes	No
<a href="#">Interim results article</a>	PAM50 subtyping and ROR score add long-term prognostic information in premenopausal breast cancer patients	09/05/2022	10/05/2022	Yes	No
<a href="#">Interim results</a>	Relationship between tamoxifen treatment and breast cancer gene expression	29/09	02/10	Yes	No

[article](#)  
[Interim](#)  
[results](#)  
[article](#)

[Protocol file](#)

Hormone receptor mRNA and protein levels

		/2023 /2023			
08/04	02/02	Yes	No		
/2024	/2026				
12/05	06/12	No	No		
/2019	/2019				