

# A double-blind, placebo-controlled study to assess the safety and efficacy of PCD-04 as a protective agent against anthracycline-induced cardiotoxicity

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|--|---|---|
| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>07/01/2021       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

A double-blind, placebo-controlled study to assess the safety and efficacy of PCD-04 as a protective agent against anthracycline-induced cardiotoxicity

### Acronym

PROTACMI

### Study objectives

Subjects in the PCD-04 arm will show less anthracyclin-induced cardiotoxicity than subjects in the placebo arm.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

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

Breast cancer

### Interventions

The patients are either randomised in the PCD-04 group or in the placebo group.

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

1. Assessment of safety: this include evaluation of general safety (blood pressure, heart rate, monitoring of the patient during infusion, laboratory tests, urinalysis)
2. Pharmacokinetics: PSD-04 plasma concentrations during study days
3. Pharmacodynamics (primary): echocardiography (ECG): left ventricular diastolic function parameters and ejection fraction

**Secondary outcome measures**

Pharmacodynamics (secondary):

1. Biochemical markers for myocardial damage
2. ECG parameters

**Overall study start date**

16/09/2003

**Completion date**

01/12/2005

**Eligibility****Key inclusion criteria**

1. Female
2. Willing and able to give written informed consent
3. Between 20 - 75 years of age
4. Scheduled for the current clinical routine protocol for adjuvant chemotherapy for carcinoma of the breast consisting of doxorubicin/cyclophosphamide cycles

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

72

**Total final enrolment**

80

**Key exclusion criteria**

1. Patients with indication of distant metastases of breast carcinoma
2. Inability to obtain a good quality echocardiogram before study drug administration
3. Patients who are unable to remain in supine condition for more than one hour
4. Patients with (a history of) malignant disease other than carcinoma of the breast
5. Patients with hepatic disorders evidenced by elevated transamines above three times the

upper limit of normal

6. Patients with a renal disorder requiring renal replacement therapy

7. Patients with a life expectancy of less than one year for whatever clinical condition

**Date of first enrolment**

16/09/2003

**Date of final enrolment**

01/12/2005

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Zernikedreef 10**

Leiden

Netherlands

2333 CL

## **Sponsor information**

**Organisation**

LTT Bio-Pharma (Japan)

**Sponsor details**

26th Floor, Atago Green Hills MORI Tower

2-5-1, Atago

Minato-ku

Tokyo

Japan

105-6201

**Sponsor type**

Industry

**Website**

[http://www.ltt.co.jp/main\\_e.html](http://www.ltt.co.jp/main_e.html)

**ROR**

<https://ror.org/016yy9j09>

# Funder(s)

## Funder type

Not defined

## Funder Name

Not provided at time of registration

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## 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="#">Results article</a> | results | 01/11/2014   | 07/01/2021 | Yes            | No              |