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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
07/01/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 then 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

Study type(s)
Not Specified

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(s)
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

Key secondary outcome(s))
Pharmacodynamics (secondary):
1. Biochemical markers for myocardial damage
2. ECG parameters

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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2333 CL

Sponsor information

Organisation
LTT Bio-Pharma (Japan)

ROR
https://ror.org/016yy9j09

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

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?
Results article	results	01/11/2014	07/01/2021	Yes	No