

# Persephone: duration of Herceptin with chemotherapy 6 versus 12 months

<b>Submission date</b> 09/02/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/09/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-comparing-6-months-and-12-months-of-trastuzumab-for-early-breast-cancer>

## Study website

<http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/cancer/persephone/>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

2006-007018-39

### IRAS number

**ClinicalTrials.gov number**

NCT00712140

**Secondary identifying numbers**

HTA 06/303/98

## **Study information**

**Scientific Title**

Persephone: duration of Herceptin with chemotherapy 6 versus 12 months

**Acronym**

Persephone

**Study objectives**

Does 6 months of trastuzumab (Herceptin®) treatment prevent breast cancer relapse (disease-free survival [DFS]) as well as 12 months of trastuzumab treatment? To test the hypothesis that reducing the duration of adjuvant trastuzumab to 6 months from 12 months, in 4,000 patients (updated 08/10/2014: originally women only) with HER-2 positive early breast cancer, produces equivalent (non-inferior) disease-free and overall survival outcomes.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/0630398>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0016/51334/PRO-06-303-98.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0016/51334/PRO-06-303-98.pdf)

On 15/01/2008 the overall trial end date was changed from 01/04/2011 to 31/03/2013.

On 08/10/2014 the overall trial end date was changed from 30/09/2014 to 30/06/2015.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

North West Research Ethics Committee, 09/08/2007, ref: 07/MRE08/35

**Study design**

Phase III randomised multi-centre trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

## **Participant information sheet**

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

HER2-positive early breast cancer

### **Interventions**

Current interventions as of 08/10/2014:

Patients will receive during or after a standard regimen of chemotherapy either:

1. The standard treatment, i.e. a dose every 3 weeks for a year (18 doses) or
2. The research treatment, i.e. 9 doses over 6 months

The starting dose of IV trastuzumab is 8 mg/kg. The maintenance dose is 6 mg/kg.  
All doses of sub-cut trastuzumab are 6 mg/kg.

Previous interventions:

Patients will receive during or after a standard regimen of chemotherapy either:

1. The standard treatment, i.e. a dose every 3 weeks for a year (17 doses) or
2. The research treatment, i.e. 9 doses over 6 months

The starting dose of trastuzumab is 8 mg/kg. The maintenance dose is 6 mg/kg.

### **Intervention Type**

Drug

### **Phase**

Phase III

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

Herceptin (trastuzumab)

### **Primary outcome measure**

Disease-free survival non-inferiority (equivalence) of 6 months trastuzumab to 12 months in early breast cancer

### **Secondary outcome measures**

1. Does 6 months of trastuzumab treatment prevent breast cancer death as well as 12 months of trastuzumab treatment?
2. What is the health economic costs and the quality of life for patients receiving 6 months versus 12 months of trastuzumab treatment?

Research will also be conducted through the collection of tissue samples

Updated 08/10/2014: Research will also be conducted through the collection of blood and tissue samples

### **Overall study start date**

01/04/2007

### **Completion date**

30/06/2015

# Eligibility

## Key inclusion criteria

1. Histological diagnosis of invasive breast cancer
2. No evidence of metastatic disease
3. Known hormone receptor status
4. Overexpression of HER-2 positive: 3+ overexpression by immunohistochemistry (IHC) or 2+ overexpression by IHC and fluorescence in situ hybridisation (FISH) test positive
5. Clear indication for chemotherapy based on clinical and histopathological features
6. Patient fit to receive any of the trial chemotherapy regimens
7. Patient must not have clinically significant cardiac abnormalities and must not have had a previous myocardial infarction during the 6 months prior to recruitment. Cardiac function should be assessed by physical examination and electrocardiogram (ECG)
8. Patient must have adequate bone marrow, hepatic, and renal function
9. No previous chemotherapy or radiotherapy
10. No previous diagnosis of malignancy unless:
  - 10.1. Managed by surgical treatment only, and disease-free for 10 years
  - 10.2. Previous basal cell carcinoma, cervical carcinoma in situ or ductal carcinoma in situ of the breast treated by surgery only
11. Non-pregnant and non-lactating
12. No concomitant medical or psychiatric problems that might prevent completion of treatment or follow-up
13. Patients 18 years or older (updated 08/10/2014; originally women only)
14. Written informed consent for the study

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Female

## Target number of participants

4,000

## Total final enrolment

4089

## Key exclusion criteria

1. Non-controlled or malignant arterial high-pressure
2. Clinically significant cardiac disease. Cardiac left ventricular ejection fraction below normal range
3. History of atrio-ventricular arrhythmias and/or congestive heart failure, even where it is under medical control, or active second- or third-degree cardiac block. History of myocardial infarct during the 6 months prior to recruitment.

4. Any co-morbidity significantly adding to risks associated with cytotoxic chemotherapy, for instance: severe chronic obstructive pulmonary disease, poorly controlled diabetes, etc.
5. History of allergy to drugs containing polysorbate 20 and the excipient TWEEN 80® and history of allergy to mouse proteins
6. Inability to comply with protocol requirements

**Date of first enrolment**

04/10/2007

**Date of final enrolment**

30/06/2015

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Addenbrooke's Hospital**

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## **Sponsor information**

**Organisation**

Cambridge Hospitals NHS Foundation Trust and Cambridge University (UK)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

## 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	20/05/2014		Yes	No
<a href="#">Results article</a>	results	29/06/2019	11/06/2019	Yes	No
<a href="#">Results article</a>	results	01/08/2020	07/09/2020	Yes	No