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Persephone: duration of Herceptin with chemotherapy 6 versus 12 months

Submission date	Recruitment status	[X] Prospectively registered
09/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/09/2020	Cancer	

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

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00712140

Clinical Trials Information System (CTIS)
2006-007018-39

Protocol serial number

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

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

Primary study design
Interventional

Study design
Phase III randomised multi-centre trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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

United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge Hospitals NHS Foundation Trust and Cambridge University (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	20/05/2014		Yes	No
Results article	results	29/06/2019	11/06/2019	Yes	No
	results				

Results article	Study website	01/08/2020	07/09/2020	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes