

HER-PCI: prospective randomised clinical trial testing the role of prophylactic cranial irradiation in patients treated with Trastuzumab (Herceptin) for metastatic breast cancer

Submission date 24/08/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/11/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-see-if-radiotherapy-can-prevent-breast-cancer-spreading-to-the-brain-in-women-treated-with-herceptin>

Contact information

Type(s)

Scientific

Contact name

Dr Peter Canney

Contact details

Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00639366

Study information

Scientific Title

HER-PCI: prospective randomised clinical trial testing the role of prophylactic cranial irradiation in patients treated with Trastuzumab (Herceptin) for metastatic breast cancer

Acronym

HER-PCI

Study objectives

Does Prophylactic Cranial Irradiation (PCI) delivering 30 Gy in ten fractions significantly reduce the incidence of symptomatic brain metastases in patients treated with Trastuzumab (Herceptin) for metastatic breast cancer?

Please note that as of 12/09/2008, the actual start date of this trial was 28th March 2007. At this time, the sponsor details were also updated. The previous sponsor was Greater Glasgow Health Board (UK).

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Glasgow Ethics Committee 1 on the 3rd October 2006 (ref: 06/S0703/108)

Study design

Open phase III randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Metastatic breast cancer

Interventions

Control arm: baseline Magnetic Resonance Imaging (MRI) of brain is required.

Experimental arm: baseline MRI of brain is required. PCI will be delivered to the whole brain giving 30 Gy in ten fractions daily. PCI will be deferred on any day that chemotherapy or Trastuzumab is administered.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Trastuzumab (Herceptin)

Primary outcome(s)

The incidence of symptomatic brain metastases

Key secondary outcome(s)

1. Survival
2. Cerebral toxicity and quality of life

Completion date

30/10/2010

Eligibility**Key inclusion criteria**

1. Histologically proven breast carcinoma which demonstrates HER2 protein level 3+ positivity on Immunohistochemistry (IHC) or level 2+ over-expression and Fluorescence In Situ Hybridisation (FISH) test demonstrating C-erbB2 gene amplification
2. Metastatic disease or locally advanced disease
3. Female
4. Aged over 18 years
5. Eastern Cooperative Oncology Group (ECOG) performance status less than two
6. Patients must a-priori be suitable for Herceptin with or without chemotherapy in terms of bone marrow, hepatic and renal function
7. Signed, written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Prior cranial radiation
2. Prior neurosurgery
3. Known or suspected brain metastases (as defined by the presence of any of the following key symptoms:
 - 3.1. Headache
 - 3.2. Nausea and/or vomiting
 - 3.3. Clinical signs of raised intracranial pressure
 - 3.4. Seizures
 - 3.5. Focal symptoms
 - 3.6. Cognitive dysfunction
 - 3.7. Affective disorder
 - 3.8. Central nervous system [CNS] disease)
4. Previous history of cerebrovascular disease or neurological disorder including seizures

Date of first enrolment

01/04/2007

Date of final enrolment

01/03/2010

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre**Beatson West of Scotland Cancer Centre**

1053 Great Western Road

Glasgow

United Kingdom

G12 0YN

Study participating centre**Ninewells Hospital**

Dundee

United Kingdom

DD1 9SY

Study participating centre**Great Western Hospital,**

Marlborough Road

Swindon

United Kingdom

SN3 6BB

Study participating centre**Western General Hospital**

Crewe Road South

Edinburgh

United Kingdom

EH4 2XU

Study participating centre
Wishaw General Hospital
50 Netherton Street
Wishaw
United Kingdom
ML2 0DP

Study participating centre
Christie Hospital
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
S10 2SJ

Study participating centre
Crosshouse Hospital
Kilmarnock Road
Crosshouse
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
St James University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Southend Hospital
Prittlewell Chase
Westcliff-on-Sea
Southend

United Kingdom
SS0 0RY

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

ROR
<https://ror.org/05kdz4d87>

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No