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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
24/08/2006		☐ Protocol	
Registration date	Overall study status Completed	Statistical analysis plan	
13/09/2006		[X] Results	
Last Edited	Condition category	Individual participant data	
27/11/2015	Cancer		

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

Protocol serial number

N/A

Study information

Scientific Title

HER-PCI: prospective randomised clinical trial testing the role of prophylactic cranial irradiation in patients treated with Trastuzmab (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 Trastuzamab (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 Trastuzemab is administered.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Trastuzmab (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-erB2 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 SSO ORY

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes