ISRCTN64624715 https://doi.org/10.1186/ISRCTN64624715

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00639366

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
The incidence of symptomatic brain metastases

Secondary outcome measures
1. Survival
2. Cerebral toxicity and quality of life

Overall study start date
01/11/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
390

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
England

Scotland

United Kingdom

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)

Sponsor details
Research and Development Central Office
The Tennent Institute
1st Floor, Western Infirmary
38 Church Street
Glasgow

United Kingdom
G11 6NT

Sponsor type
Government

Website
http://www.nhsgg.org.uk/content/default.asp

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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
Available on request

Study outputs

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