ISRCTN82811952 https://doi.org/10.1186/ISRCTN82811952

HERA: A randomised three-arm multi-centre comparison of 1 year and 2-years of Herceptin® versus no Herceptin® in women with HER2-positive primary breast cancer who have completed adjuvant chemotherapy

Submission date
15/10/2002

Recruitment status
No longer recruiting

Registration date
15/10/2002

Overall study status
Completed

Last Edited
22/10/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00045032

Study information

Scientific Title
HERA: A randomised three-arm multi-centre comparison of 1 year and 2-years of Herceptin® versus no Herceptin® in women with HER2-positive primary breast cancer who have completed adjuvant chemotherapy

Acronym
HERA

Study objectives
Added 08/09/09:
Monoclonal antibodies such as trastuzumab can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. It is not yet known whether trastuzumab is effective in treating primary breast cancer in women who have completed adjuvant chemotherapy.

Primary objectives:
1. Compare the disease-free survival of women with HER2-positive primary breast cancer treated with trastuzumab (Herceptin®) for 1 year vs trastuzumab for 2 years vs standard supportive care.
2. Compare the overall survival of patients treated with these regimens.
3. Compare the relapse-free survival of patients treated with these regimens.
4. Compare the distant disease-free survival of patients treated with these regimens.
5. Compare the incidence of cardiac dysfunction in patients treated with these regimens.
6. Evaluate the safety and tolerability of these regimens in these patients.

Secondary objectives:
1. Compare time to recurrence in patients treated with these regimens.
2. Compare time to distant recurrence in patients treated with these regimens.
3. Compare outcomes, in terms of disease-free survival, overall survival, recurrence-free survival, distant disease-free survival, time to recurrence, time to distant recurrence, cardiac safety, and overall safety, in patients treated with trastuzumab for 1 year vs 2 years.

Please note that as of 08/09/09 this record has been extensively updated. All updates can be found under the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Multicentre randomised open label controlled parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions
Current information as of 08/09/09:
This is a randomised, open-label, multicentre study. Patients are stratified according to nodal status (any nodal status and prior neoadjuvant chemotherapy vs no positive nodes and no prior neoadjuvant chemotherapy vs 1-3 positive nodes and no prior neoadjuvant chemotherapy vs 4 or more positive nodes and no prior neoadjuvant chemotherapy), prior adjuvant chemotherapy regimen (no anthracyclines or taxanes vs anthracyclines only vs anthracyclines and taxanes), receptor status and endocrine therapy (negative vs positive and no prior endocrine therapy vs positive and prior endocrine therapy), age (18 to 34 vs 35 to 49 vs 50 to 59 vs 60 and over), and participating center. Patients are randomized to 1 of 3 treatment arms.

1. Arm I: Patients receive trastuzumab (Herceptin®) IV over 1.5 hours on day 1. Courses repeat every 3 weeks for up to 1 year in the absence of disease progression or unacceptable toxicity.
2. Arm II: Patients receive trastuzumab as in arm I. Courses repeat every 3 weeks for up to 2 years in the absence of disease progression or unacceptable toxicity.
3. Arm III: Patients receive no trastuzumab. Patients may later receive trastuzumab as in arm I or arm II. Patients are followed every 3 months for 2 years, every 6 months for 3 years, and then annually thereafter.

Initial information at time of registration
1. Patients are randomised to receive Herceptin® every 3 weeks for 1 or 2 years
2. No further treatment

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Tratuzumab (Herceptin®)

Primary outcome(s)
Added 08/09/09:
1. Disease-free survival
2. Relapse-free survival
3. Distant disease-free survival
4. Incidence of cardiac dysfunction
5. Safety and tolerability

Key secondary outcome(s)
Added 08/09/09:
1. Overall survival
2. Time to recurrence
3. Time to distant recurrence

Completion date
01/12/2004

Eligibility

Key inclusion criteria
1. Females aged ≥18 years
2. Eastern Cooperative Oncology Group (ECOG) performance status ≤1
3. Non-metastatic operable primary invasive adenocarcinoma of the breast that is histologically confirmed, adequately excised and axillary node positive or negative
4. Known hormone receptor status
5. Completion of at least 3 months of an approved (neo-) adjuvant chemotherapy regimen
6. Baseline left ventricular ejection fraction (LVEF) ≥55%
7. Completion of radiotherapy for any patients undergoing radiotherapy
8. Overexpression of HER2 in the invasive component of the primary tumour
9. Completion of all necessary baseline lab and radiological investigations
10. 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
Does not match inclusion criteria

Date of first enrolment
01/03/2002

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Austria

Belgium

Brazil

Canada

Chile

China

Colombia

Croatia

Denmark

France

Germany

Greece

Guatemala

Hong Kong

Hungary

Ireland

Israel

Italy

Japan

Netherlands

Poland

Portugal

Russian Federation

Singapore

South Africa

Spain

Sweden

Switzerland

Thailand

Study participating centre
UKCCCR Register Co-ordinator
London
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Sponsor information

Organisation
Roche Products Limited (UK)

ROR
https://ror.org/024tgbv41

Funder(s)

Funder type
Industry

Funder Name
Roche Products Ltd (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 results	20/10/2005		Yes	No

Results article		06/01/2007	Yes	No
Results article	results on adverse cardiac effects	01/09/2007	Yes	No
Results article	results	01/06/2008	Yes	No
Results article	results	20/06/2009	Yes	No
Results article	results	20/07/2010	Yes	No
Plain English results			No	Yes