

Comparison of vinorelbine versus docetaxel, and trastuzumab versus no trastuzumab as adjuvant treatments of early breast cancer

Submission date 18/03/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/11/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

FBCG 00-01

Study information

Scientific Title

Comparison of vinorelbine versus docetaxel, and trastuzumab versus no trastuzumab as adjuvant treatments of early breast cancer

Acronym

FinHer

Study hypothesis

The purpose of the trial is to compare tolerability, safety and efficacy of single-agent vinorelbine and single-agent docetaxel as adjuvant treatments of early breast cancer with moderate to high risk for cancer recurrence. The trial also assesses tolerability, safety and efficacy of trastuzumab given concomitantly with vinorelbine or docetaxel as adjuvant treatment of early breast cancer with moderate to high risk for cancer recurrence.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Condition

Breast cancer

Interventions

Randomisation:

1. Between weekly vinorelbine $25 \text{ mg/m}^2 \times 8$ followed by cyclophosphamide, epirubicin and 5-fluorouracil (CEF) $\times 3$ vs three weekly docetaxel $100 \text{ mg/m}^2 \times 3$ followed by CEF $\times 3$
2. Whenever tumor is HER2-positive, a second randomization between weekly trastuzumab 2 mg/kg concomitantly with vinorelbine/docetaxel versus no trastuzumab

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Vinorelbine, docetaxel, and trastuzumab

Primary outcome measure

Disease-free survival

Secondary outcome measures

Survival, safety, quality of life, cardiac ejection fraction

Overall study start date

01/11/2000

Overall study end date

31/08/2003

Eligibility**Participant inclusion criteria**

1. Histologically confirmed breast cancer
2. Age 65 or less
3. Progesterone receptor (PgR) and human epidermal growth factor receptor two (HER2) status available
4. M0
5. Written informed consent
6. Estimated risk of breast cancer recurrence more than 25% within the first five years from the diagnosis: pN+ or pN0 with tumor size more than 20 mm and PgR negative

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

1010

Participant exclusion criteria

1. Special type of histology without axillary lymph node metastases
2. World Health Organisation (WHO) performance status (PS) more than one
3. Blood leukocyte count less than 3.0 or granulocyte count less than 1.5, thrombocyte count less than 120

4. Severe cardiac disease or hypertension
5. Severe liver disease
6. Pregnancy
7. Male breast cancer
8. More than 12 weeks between breast surgery and study entry
9. Prior cancer except for basalioma/any in situ cancer

Recruitment start date

01/11/2000

Recruitment end date

31/08/2003

Locations

Countries of recruitment

Finland

Study participating centre

Department of Oncology

Helsinki

Finland

FIN-00029

Sponsor information

Organisation

Finnish Breast Cancer Group, HYKS Institute

Sponsor details

HYKS-Institute

Haartmaninkatu 8

P.O. Box 700

Helsinki

Finland

FIN-00029

Sponsor type

Charity

Website

<http://www.hus.fi>

ROR

<https://ror.org/02e8hzf44>

Funder(s)

Funder type

Charity

Funder Name

Sponsored by the Finnish Breast Cancer Group; supported by Sanofi-Aventis, Pierre-Fabre, Pharmacia; HYKS Institute Project Number 2161

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/02/2006		Yes	No
Results article	results	01/12/2009		Yes	No
Results article	results	01/08/2014		Yes	No
Results article	results	26/02/2018		Yes	No
Results article	results	01/07/2018	20/11/2019	Yes	No