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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/04/2005	**Overall study status** Completed	
Last Edited 20/11/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 objectives
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

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Randomisation:
1. Between weekly vinorelbine 25 mg/m^2 x 8 followed by cyclophosphamide, epirubicin and 5-fluorouracil (CEF) x 3 vs three weekly docetaxel 100 mg/m^2 x 3 followed by CEF x 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

Completion date
31/08/2003

Eligibility

Key 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

Key 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

Date of first enrolment
01/11/2000

Date of final enrolment
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