ISRCTN10059974 https://doi.org/10.1186/ISRCTN10059974

A randomised phase II study of cytotoxic chemotherapy or cytotoxic chemotherapy combined with celecoxib or trastuzumab as primary chemotherapy for patients with high risk localised breast cancer not amenable to breast conserving therapy

Submission date
17/11/2006

Recruitment status
No longer recruiting

Registration date
08/02/2007

Overall study status
Completed

Last Edited
01/02/2019

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

Protocol serial number

Remagus 0002

Study information

Scientific Title
A randomised phase II study of cytotoxic chemotherapy or cytotoxic chemotherapy combined with celecoxib or trastuzumab as primary chemotherapy for patients with high risk localised breast cancer not amenable to breast conserving therapy

Study objectives
Addition of celecoxib or trastuzumab to neoadjuvant cytotoxic chemotherapy could increase the pathological response rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval granted from the local ethics committee (Comités de Consultation pour la Protection des Personnes se prêtant à la Recherche Biomédicale [CCPPRB] Paris Nord) on 14/10/2003.

Study design
Open phase II interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Localised breast cancer not amenable to breast conserving therapy

Interventions
Control arm:
Cytotoxic chemotherapy consisting of Epirubicin 75 mg/sqm and cyclophosphamide 750 g/sqm every three weeks for four cycles, followed by docetaxel 100 mg/sqm every three weeks for four cycles, followed by breast surgery.

Test arm:
Same cytotoxic chemotherapy combined with celecoxib 800 mg/d given during cycles five to eight (Human Epidermal growth factor Receptor (HER2) negative), or trastuzumab 8 mg/kg loading dose then 6 mg/kg every three weeks with docetaxel (cycles five to eight), followed by breast surgery.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Celecoxib, trastuzumab and cytotoxic chemotherapy (epirubicin, cyclophosphamide and docetaxel)

Primary outcome(s)
Pathological response rate

Key secondary outcome(s))
1. Clinical response rate
2. Safety

Completion date
15/09/2007

Eligibility

Key inclusion criteria
1. Pathologically proven T1c-T4, N0-N1, M0 invasive breast cancer (Tumour, Nodes, Metastasis [TNM] classification)
2. No prior therapy
3. Age 18 to 65 years
4. Available frozen tumour tissue
5. 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. Male patient
2. Prior therapy for breast cancer
3. Contraindication to study drug(s)
4. Stage IV breast cancer

Date of first enrolment
14/10/2003

Date of final enrolment
15/09/2007

Locations

Countries of recruitment
France

Study participating centre
Centre for Therapeutic Innovations in Oncology and Haematology (CITOH)
Paris
France
75010

Sponsor information

Organisation
Remagus (France)

Funder(s)

Funder type
Government

Funder Name
French government (ref: AOM/2002/02117)

Funder Name
Support from Sanofi-Aventis, Roche Pharma and Pfizer

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 on pre- and post- therapy detection of circulating tumor cells	01/04/2010		Yes	No
Results article	main results	01/07/2010		Yes	No
Results article	results	01/06/2011		Yes	No
Results article	results	10/03/2019	01/02/2019	Yes	No