

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Pathological response rate

Secondary outcome measures

1. Clinical response rate
2. Safety

Overall study start date

14/10/2003

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

340

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

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Sponsor information

Organisation

Remagus (France)

Sponsor details

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Sponsor type

Government

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

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 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