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A phase III multicentre double blind randomised trial of celecoxib versus placebo in primary breast cancer patients

Submission date 12/01/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/02/2004	**Overall study status** Completed	
Last Edited 23/09/2021	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-celecoxib-for-women-with-breast-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02429427

Protocol serial number
ICCG C/20/01, GBG 27, BIG 1- 03

Study information

Scientific Title
A phase III multicentre double blind randomised trial of celecoxib versus placebo in primary breast cancer patients

Acronym
REACT

Study objectives
The primary aim is to assess the disease-free survival benefit of two years adjuvant therapy with the cyclooxygensase-2 (COX-2) inhibitor celecoxib compared with placebo in primary breast cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Medical Research Ethics Committee on 19/12/2005

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Interventions criteria has been amended as of 19th December 2005:
Arm A: placebo twice daily for a total of two years
Arm B: 400 mg celecoxib once daily for a total of two years

1. Randomisation is 2:1 in favour of arm B
2. All ER+ and/or Progesterone Receptor positive (PgR+) patients will also receive tamoxifen (20 mg daily) for two to three years followed by exemestane (25 mg daily) for a further two to three years (total endocrine treatment should be for a duration of five years)

Previous interventions criteria:
Arm A: placebo twice daily for a total of two years
Arm B: 400 mg celecoxib twice daily for a total of two years

1. Randomisation is 2:1 in favour of arm B
2. All ER+ and/or PgR+ (Progesterone Receptor) patients will also receive exemestane 25 mg daily for a duration of five years

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
1. Celecoxib 2. Tamoxifen 3. Exemestane

Primary outcome(s)
Disease Free Survival (DFS) benefit of two years adjuvant therapy with celecoxib compared with placebo in primary breast cancer patients

Key secondary outcome(s))
Overall survival, toxicity associated with long-term use of celecoxib in primary breast cancer patients, cardiovascular mortality and incidence of second primaries

Completion date
01/03/2016

Reason abandoned (if study stopped)
The old trial was stopped because the EMEA was to carry out a six month review of all the data they had for COX-2 inhibitors following the time when VIOXX was taken off the market

Eligibility

Key inclusion criteria
Inclusion criteria amended as of 19th December 2005:
1. Resected node positive or high-risk node negative breast cancer (St Gallen 2001 criteria)
2. Postmenopausal or Estrogen Receptor (ER) negative premenopausal
3. If (neo) adjuvant chemotherapy has been received then at least four cycles should have been completed
4. Entry into study must be greater than or equal to 28 days after the end of chemotherapy and within 12 weeks of day one of last cycle of adjuvant chemotherapy, or within six weeks of the end of radiotherapy (whichever is last)
5. Normal baseline Electrocardiogram (ECG) and normal clinical cardiovascular assessment after completion of all (neo) chemotherapy and radiotherapy

Previous inclusion criteria:
1. Resected node positive or high risk node negative breast cancer (St Gallen 2001 criteria)
2. Postmenopausal or ER (Estrogen Receptor) negative premenopausal
3. Completion of at least four cycles (neo) adjuvant chemotherapy greater than or equal to 28 days after end of chemotherapy and within 12 weeks of day one of last cycle of adjuvant chemotherapy, or within six weeks of end of radiotherapy (whichever is last)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
2639

Key exclusion criteria
1.Active or previous peptic ulceration or GastroIntestinal (GI) bleeding in the last year
2. Known or suspected congestive heart failure (New York Heart Association [NYHA] classification greater than one) and or coronary heart disease, previous Myocardial Infarction (MI), uncontrolled arterial hypertension (i.e. Blood Pressure (BP) greater than 160/90 mmHg under treatment), rhythm abnormalities requiring permanent treatment
3. Past history of stroke, Transient Ischaemic Attack (TIA) or peripheral vascular disease
4. C-Erb-B2 +++ or Fluorescent In Situ Hybridisation (FISH) positive

Date of first enrolment
01/03/2006

Date of final enrolment
01/03/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College of Science, Technology and Medicine
London
United Kingdom
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Sponsor information

Organisation
Imperial College of Science and Technology (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Industry

Funder Name
Pfizer UK

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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		15/07/2021	16/07/2021	Yes	No
Abstract results	conference abstract:	01/03/2009		No	No
Abstract results	conference abstract:	20/05/2011		No	No
Abstract results	results in conference abstract:	15/02/2018		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes