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Phase III randomised double-blind placebo controlled study of rofecoxib (VIOXX) in colorectal cancer patients following potentially curable therapy

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 11/08/2011	**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

NCT00031863

Secondary identifying numbers
VICTOR

Study information

Scientific Title

Acronym
VICTOR - Vioxx In Colorectal cancer Therapy: definition of Optimal Regime

Study objectives
Added as of 24 January 2008:
1. Treatment with VIOXX® will result in improved overall survival compared with placebo
2. Treatment with VIOXX® will result in improved disease-free survival compared with placebo

Countries of recruitment amended as of 26 July 2007: Countries of recruitment provided at time of registration: International

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 26 July 2007: Approved by Clinical Trials Committee of the Cancer Research Campaign, the West Midlands Multicenter Research Ethics Committee, and local research ethics committees at participating centers.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions

1. VIOXX: 25 mg once daily
2. Placebo: identical in appearance, once daily

As of 26 July 2007: Please note that this trial was terminated prematurely in September 2004 due to worldwide withdrawal of rofecoxib.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Vioxx (rofecoxib)

Primary outcome measure
Added as of 24 January 2008:
Overall Survival

Secondary outcome measures
Added as of 24 January 2008:
1. Relapse-free survival
2. Thrombotic cardiovascular safety

Overall study start date
30/04/2002

Completion date
30/09/2004

Reason abandoned (if study stopped)
Vioxx withdrawn

Eligibility

Key inclusion criteria
1. Histologically proven Dukes Stage C (Stage III any T, N1-2, M0) or B (Stage II, T3 or 4, N0, M0) colorectal carcinoma
2. Complete resection of primary tumour without gross microscopic evidence of residual disease
3. World Health Organisation zero to one
4. Acceptable haematological and biochemical function
5. Within 12 weeks of finishing potentially curative therapy (Surgery +/- radiotherapy +/- chemotherapy)
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
7000

Key exclusion criteria
Exclusion criteria added as of 26 July 2007:
1. Active peptic ulceration or gastrointestinal bleeding in the past year
2. History of adverse reactions to NSAIDs
3. Known sensitivity to rofecoxib
4. Those receiving long-term NSAID therapy (except for low-dose aspirin, =100 mg per day)
5. Younger than 18 years
6. Women who were pregnant, lactating, or premenopausal but not using contraception. 7. History of cancer (other than adequately treated in situ carcinoma of the cervix or basal or squamous-cell carcinoma), inflammatory bowel disease, or severe congestive heart failure

Date of first enrolment
30/04/2002

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Clinical Pharmacology
Oxford
United Kingdom
OX3 7DQ

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford

England
United Kingdom
OX1 2JD
+44 (0)1865 270 000
research.services@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Merck and Co Inc

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	26/07/2007		Yes	No