

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

<b>Submission date</b> 01/07/2001	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/07/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/08/2011	<b>Condition category</b> 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

Prof David J Kerr

### Contact details

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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?
<a href="#">Results article</a>	Results	26/07/2007		Yes	No