

29 Dec 2010

Dear Researcher

Tel: +44 (0) 1865 617000
E-mail: enquiries@octo-oxford.org.uk

Re: Research Protocol: Phase III, randomised, double blind, placebo controlled study of ROFECOXIB (VIOXX*) in colorectal cancer patients following potentially curative therapy. The VICTOR Trial

EudraCT: 2004-000657-39

We are writing to provide you with the VICTOR publication and editorial recently published in the Journal of Clinical Oncology. We would like to take this opportunity to thank you and your team for all the hard work performed in recruiting patients, data collection, provision of samples and patience with the changes throughout the duration of the trial. Your assistance throughout the trial has been greatly appreciated.

The purpose of this trial was to test whether the COX-2 inhibitor rofecoxib could reduce recurrence and improve survival when administered in the adjuvant setting of colorectal cancer.

Between April 2002 and September 2004, 2,434 patients were successfully recruited for the VICTOR Trial at 151 hospitals in the United Kingdom.

Patients who had undergone potentially curative surgery and completion of adjuvant therapy for stage II and III CRC were randomly assigned to receive rofecoxib (20 mg daily) or placebo. The primary end point was overall survival (OS).

The trial was terminated early because of the worldwide withdrawal of rofecoxib. At this point, 1,167 patients had received rofecoxib and 1,160 patients had received placebo for median treatment durations of 7.4 and 8.2 months, respectively.

For the rofecoxib and placebo arms, median follow-up times were 4.84 and 4.85 years, with 241 and 246 deaths, and 297 and 329 recurrences, respectively.

In this study of abbreviated therapy in the adjuvant setting of CRC, rofecoxib did not improve OS or protect from recurrence in unselected patients. In addition, COX-2 expression did not correlate with prognosis overall or predict effectiveness of COX-2 inhibitors.

In general, rofecoxib was well tolerated apart from the enhanced cardiovascular adverse event profile, which could likely be avoided by better patient selection. There is still significant interest in the potential role of COX-2 inhibition in cancer secondary prevention and a further trial of this family of drugs with careful patient selection, maintenance of exposure and a careful parallel assessment of biomarkers is worthy of consideration.

If you have any queries please do not hesitate to contact us at the Oncology Clinical Trials Office office on 01865 6170000.

Yours sincerely,



David J Kerr, CBE, MA MD DSc FRCP (Glas & Lon) FMedSci
Rhodes Professor of Cancer Therapeutics and Clinical Pharmacology
Director, National Translational Cancer Research Network



Dr Rachel Midgley