

Victor trial informed consent sheet 2004

This material is from a 2005 investigation by [Brian Deer](#) for The Sunday Times of London into the painkiller **Vioxx** | Go to [Vioxx index](#)

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To be put on hospital headed paper

VICTOR: Phase III, randomised, double blind, placebo-controlled study of rofecoxib (VIOXX®) in colorectal cancer patients following potentially curative therapy.

PATIENT INFORMATION SHEET

Although you have completed surgery, and perhaps chemotherapy or radiotherapy successfully, there is still a possibility that there could be some cancer cells left. We would like to invite you to take part in a study to work out if a new type of tablet, which has been used to treat arthritis, might cut down the chances of bowel cancer coming back.

This information sheet is designed to help you understand what the study is about. Please take time to read the following information carefully. You may take this sheet away with you to read and discuss with your doctor, nurses, relatives and friends, if you wish. If anything is not clear or if you would like some more information, please contact your doctor or nurse.

Taking part in this research is entirely voluntary.

What is the purpose of the study?
Studies carried out in patients and animals have shown that traditional Non-Steroidal Anti Inflammatory Drugs (NSAIDs) such as aspirin, can protect against bowel cancer. These drugs have not been widely used because of heartburn, indigestion and, rarely, bleeding from the stomach.
Recently a new type of drug has been developed, which has less gastrointestinal side effects than traditional NSAIDs. These drugs have been shown to be more effective than traditional NSAIDs in preventing bowel tumours in animals. There is evidence from laboratory studies that one of these new drugs, VIOXX®, can kill bowel cancer cells and stop tumour nodules growing.
In this study we are trying to find out if the new NSAID VIOXX® can cut down the chance of bowel cancer coming back. We are also interested in finding out how long patients should continue to take the tablets, so a computer will choose, at random, whether you will take the treatment for two years or five years.

Why have I been chosen?
You have been chosen because although you have completed surgery and perhaps chemotherapy or radiotherapy successfully, there is still a possibility that there could be some cancer cells left. Other patients with bowel cancer, elsewhere in the UK and other countries, will be invited to join the trial. We need to study 7000 patients like you.

Do I have to take part?
Participation in the trial is entirely voluntary. Your standard of care will not be affected if you decide not to take part in this study.
You will be given time to consider taking part in the study. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. You are free to withdraw at any time and without giving a reason. This will not in any way affect any future care you will receive from your medical and nursing team.

What will happen to me if I take part?
We are inviting patients, like you, to join a randomised trial. Randomisation means that neither you nor your doctor picks the treatment, but a computer will decide, so that the results of the trial are as reliable as possible. Half of the patients in the trial will receive VIOXX®, while the other half will receive a dummy tablet. Because the tablets are identical in appearance, neither you nor your doctor will know if you are receiving the active tablet (VIOXX®) or the dummy tablet (placebo).

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If you agree to take part in the trial, having read and understood this information sheet and had any questions answered, you will be asked to sign a form to agree to take one tablet daily for 2 or 5 years. You will be given a copy of the consent form to keep along with this information sheet. We will telephone the trials office who will randomise you to one of the four available treatment choices. This will determine which tablets you will receive.

- Either
- A- VIOXX® tablets for 2 years
 - B- Placebo tablets for 2 years
 - C- VIOXX® tablets for 5 years
 - D- Placebo tablets for 5 years

You may be asked to have a heart tracing (ECG) prior to taking the first tablet, if you have not had one in the last year. This will enable us to collect baseline information about your heart activity so that we can monitor your general health.

A member of the trial team at your hospital will call you after you have started taking the tablets to make sure that you are happy to continue. You may be asked to visit the outpatient clinic or telephoned by your study nurse at 3 months, 6 months, 1 year, 18 months, 2 years after randomisation and annually thereafter according to local practice. Your doctors will then see you regularly to monitor your progress, according to their usual practice

What do I have to do?

While taking the study medication you should not take any non-steroidal anti-inflammatory drugs e.g. aspirin and ibuprofen, unless advised by your doctor. We will give you a small card that details the drugs which you should avoid- please show this to your pharmacist if you are unsure.

If you have had any previous heart trouble (a heart attack or severe angina) or a stroke your doctor may have prescribed aspirin to prevent any further problems. It is important to keep taking these tablets, as the VICTOR trial medication is not a substitute. If your heart condition gets any worse, please consult your own doctor.

You will need to use an adequate form of contraception to ensure that you do not become pregnant during the study.

You will be asked to take the trial tablets regularly. There should be no other restrictions to your lifestyle.

What is the drug that is being tested?

The drug that is being tested is a tablet called VIOXX® that is taken by mouth. So far VIOXX® has been used to treat patients with arthritis at a dose of 25 mg daily.

You will be given a card to say that you are taking part in a clinical trial. The card will advise you, your doctor and your pharmacist what medication you should avoid whilst taking part in this study. Please carry the card with you at all times and show it to your doctor or pharmacist if you require any treatment during the study.

What are the alternatives for treatment?

There is no clinically proven and accepted alternative to the treatment being assessed in this trial. If you do not wish to take part then you would continue under the care of your doctor without having the treatment being assessed here.

What are the possible side effects of taking part?

Several thousand patients have been treated with VIOXX® around the world and it is considered to be safer than many existing similar painkillers. However the following side effects have been described, affecting less than 10% of treated patients:

- Tummy pain
- Indigestion and heartburn
- Dizziness
- Nausea and diarrhoea
- Fluid retention leading to ankle swelling
- Mild headache
- Increase in blood pressure
- Itching

The following side effects have been seen less often, affecting less than 1% of patients:

- Swollen tummy and wind
- Constipation and acid indigestion
- Vomiting
- Mouth ulcer
- Tiredness (sometimes caused by anaemia)
- Chest pain
- Ringing in the ears
- Feeling drowsy
- Change in blood tests that may mean that the kidneys and liver are not working as well as usual.
- Weight gain
- Muscle cramps
- Difficulty getting to sleep
- Depression
- Difficulty in breathing
- Skin rash
- Difficulty concentrating

There is a very small risk that taking VIOXX® for long periods of time can cause peptic ulcers and bleeding from the stomach (between 1 in ten thousand and 1 in a thousand).

If you experience persistent dizziness or drowsiness (i.e. for more than 1 week) whilst taking the trial medication you should avoid driving or operating machinery and inform your doctor.

If you are taking warfarin to stop your blood clotting, you will need to be closely monitored by your doctor to make sure that your dose is correct. If you experience any other symptoms you should report them to your doctor.

What are the potential disadvantages and risks of taking part?

Because the study drug may be harmful to an unborn child, as a woman you must agree to use an adequate form of birth control during this study e.g. oral contraceptive pill, diaphragm, condom. If you are pregnant you may not enter into this study. If you were to become pregnant you must notify your study doctor immediately.

There is a possibility that taking part in this study may affect any private medical insurance that you may have. If you are at all worried about this, please contact your insurance company.

What are the possible benefits of taking part?

The purpose of the trial is to find out if taking VIOXX® tablets reduces the chance of the bowel cancer coming back. There are no guarantees that this will be the case. The information we get from this study may help us to treat patients with bowel cancer better in the future.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the drug that is being studied. If this happens, your research doctor will tell you about it and discuss whether you want to continue in the study. If you decide to withdraw your doctor will make arrangements for your care to continue. If you decide to continue in the study you may be asked to sign an updated consent form.

On receiving new information your doctor may consider it to be in your best interests to withdraw you from the study. Your doctor will explain the reasons and arrange for your care to continue.

What happens when the research study stops?

When your treatment comes to an end after 2 or 5 years, your own doctors will see you regularly for follow up in their outpatient clinics, according to their usual routine.

What if something goes wrong?

You will receive the best medical care available during and after the trial, but because these are still relatively new treatments, unexpected side effects may occur. In the unlikely event of an injury arising from taking part in this trial, you will be provided with the necessary care.

Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking the ABPI guidelines recommend that 'the sponsor', without legal commitment, should compensate you without you having to prove that it is at fault. This applies in cases where it is likely that such injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study. 'The sponsor' will not compensate you where such injury results from any procedure carried out which is not in accordance with the protocol for the study. Your right at law to claim compensation for injury where you can prove negligence is not affected. Copies of these guidelines are available on request.

If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedure mechanisms may be available to you. Your doctor will give you further information if necessary.

Will my taking part in this study be kept confidential?

Information collected about you during the trial will be kept at the VICTOR Trial Office, which is part of the University of Oxford. This information is strictly confidential.

Unless required by law, only your doctor (Investigator), the VICTOR Trial Office (University of Oxford) staff (sponsor), Merck & Co. Inc. (drug manufacturer) and worldwide government regulatory agencies will have access to confidential data, which identifies you by name. This is so that we can check that the study is being carried out correctly. Any information that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

Your GP and any other doctors who may treat you, but who are not involved in the study, will be notified that you are taking part in the study.

What will happen to the results of the research study?

Results of the trial will be published in medical journals, but the confidentiality of all patients will be maintained. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please ask your doctor.

Blood and tissue samples

The VICTOR trial gives us an opportunity to perform tests on the cancer that was removed at the time of surgery and to take an additional blood sample (maximum 50 ml of blood, equal to about 3 tablespoons) that may give us extra information on why some people are more sensitive to side effects of drug treatment for cancer, and even why some people develop cancer in the first place. You may refuse permission if you don't want those extra samples to be taken.

Tissue:

Scientific advances mean that we are constantly finding new tests that we can apply to the cancer tissue that was removed at the time of surgery. These tests, might tell us which cancers are more likely to respond to drug treatment, or what causes some cancers to spread or grow more quickly than others. It is not possible to give a complete list of the tests we will perform because as our scientists discover more about cancer, we will be able to try new tests. This is because we can store the cancer tissue for many years and use only tiny fragments for the lab tests. It is likely that some of the cancer tissue will be used for research with drug companies in the search for new treatments, which could lead to commercial gain for the company. When you consent to let us use your tissue for research, we would like to make it clear that you would not be entitled to any financial gain.

Blood:

We would like to take an extra blood sample, which we will use to make DNA. DNA is the chemical that makes up genes, the factors that we inherit from our parents that determine our characteristics (height, hair colour, appearance etc.). There is growing evidence that we can also inherit an increased chance of developing certain diseases, including cancer. Scientists who are experts in genomics would like to perform tests on the DNA collected from your blood - these could give us information on which genes might cause cancer, or increase the chance of side effects from drugs. Genetic science is changing rapidly and, like the tissue tests, we would like permission to use new tests, when they appear in the future.

We will store the tissue and blood in a central laboratory using a code, not your name, to identify the sample. We set up a small committee of scientists and doctors to make sure that the tissue and blood (DNA) will only be made available to researchers working to the highest ethical standards. In the trial we will be monitoring your treatment and progress, and we can use the code to link the tissue/blood samples to the information that we collect during the trial. However, we will keep you anonymous and the researchers working with your tissue/blood will never know your name.

Who is organising and funding the research?

The study is being organised and funded by the VICTOR Trial Office (University of Oxford), with an educational grant provided by Merck & Co.

Who has reviewed the study?

The study has been reviewed by the Cancer Research Campaign Clinical Trials Committee (now Cancer Research UK), the West Midlands Multi-centre Research Ethics Committee and your Local Research Ethics Committee.

What if I have more questions or haven't understood something?

Please feel free to ask any further questions of the doctors and nurses looking after you before deciding to take part in the trial or at any time during the study.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW.

Thank you for reading this information sheet.

Your local contact is: _____ Tel: _____

Independent contact is: _____ Tel: _____