Bladder COX-2 Inhibition Trial

A randomised phase III placebo-controlled trial evaluating the addition of celecoxib to standard treatment of transitional cell carcinoma of the bladder

Summary of Results

Some time ago you agreed to take part in a clinical trial called the BOXIT trial.

The aim of the BOXIT trial was to test whether a product called celecoxib would help to stop bladder cancer returning.

You were one of 472 people who joined the study between November 2007 and July 2012. The study was conducted in 51 hospitals in the UK.

The main results of the trial are now available and are explained in this leaflet.

Background

When you consented to take part in the BOXIT trial you were allocated at random to one of the following treatment groups:

The 2 groups are as follows:

1) Standard treatment* and celecoxib for 2 years
2) Standard treatment* and Placebo for 2 years (A placebo is a dummy tablet that looks like the real thing but does not contain any active ingredients.)

*Standard treatment will be Mitomycin-C (MMC) alone or MMC plus BCG

Data from the clinic appointments that you kindly attended over a number of years have been collected and analysed at the Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU). The results have been published in a leading medical journal so that doctors around the world can be made aware of the findings. The results compare the groups of patients and you cannot be identified in any of the publications.

The results:

Bladder cancer control
The BOXIT trial did not show a difference in time to bladder cancer recurrence between the two treatment arms. Celecoxib was not shown to reduce the risk of recurrence in intermediate or high risk non-muscular invasive bladder cancer although celecoxib was associated with delayed time to recurrence in a sub group of patients with high risk (pT1) non-muscle invasive bladder cancer.

Side effects
In December 2013, the trial was stopped, as the chances of there being any benefit in continuing to take study medication were considered very small, and we identified a small increased risk of cardiovascular event in patients on celecoxib. Any patient who was still receiving treatment at this time was asked to stop their study medication for this reason only. There were no unexpected toxicity concerns and in particular the cardiovascular risk of taking study medication in BOXIT was in line with that envisaged at the start of the study and as described in the BOXIT patient information sheet.

However, at that time there were still some other important questions to answer in the BOXIT trial and we continued to follow-up BOXIT patients who attended for their clinic visits. Follow-up of patients has continued until the data was mature enough for analysis.

The final analysis of the BOXIT trial has now occurred and this confirmed that there was no difference shown between the two treatment groups and cardiac events were more common with celecoxib. Therefore, the results of BOXIT do not support the use of celecoxib in bladder cancer patients.

What will happen now?

We will continue to follow up of all patients who entered the BOXIT trial so that we are able to assess disease control.

Many patients in the study agreed to donate a small sample of tissue left over from their bladder cancer diagnosis or recurrence and blood and/or urine samples for laboratory research. We have collected these samples from participating hospitals and these remain at University College London.

The BOXIT trial has received funding from Cancer Research UK. The Chief Investigator is Professor John Kelly of the University College London. BOXIT is coordinated by the Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU).

Thank you for taking part in BOXIT. Without the contribution of people like you, this trial would not have been possible. If you have any questions about the results of BOXIT, please discuss this information sheet with your consultant who will be happy to help you.

Local Consultants name:

Address:

Telephone: