



First results of the 111 trial: A single group trial evaluating one cycle of adjuvant BEP chemotherapy in high risk, stage 1 non-seminomatous germ cell tumours of the testis

You previously agreed to take part in a clinical trial called the 111 trial, a study in stage one non-seminomatous testicular cancer that had a high risk of returning after surgery.

The 111 trial aimed to find out whether using one cycle of BEP chemotherapy worked as well as two cycles at preventing the cancer from returning.

The results are now available and are described below.

Background

Everybody who consented to take part in the 111 trial was treated with one cycle of BEP chemotherapy after the testicle had been removed. BEP chemotherapy is a combination of three drugs: bleomycin, etoposide and cisplatin.

Data from the clinic appointments that you attended during the study have been collected and analysed at the Clinical Trial and Statistics Unit at The Institute of Cancer Research (ICR-CTSU). These results have been presented at an international conference and have been published in a leading medical journal so that doctors around the world can be made aware of the findings. You cannot be identified personally from any of the data used in any of the presentations or publications.

The full results publication is available at the following web address:

<https://doi.org/10.1016/j.eururo.2019.11.022>

The results:

Participation in the study

236 men joined the 111 trial between February 2010 and March 2014 and received one cycle of BEP chemotherapy. These participants came from 33 NHS hospitals across the UK.

How well did one cycle of BEP work?

We found that within two years after treatment three participants' cancer returned. This meant the risk of the cancer coming back within two years after treatment is just over 1 out of 100, which is very similar to the risk after two cycles. So our results show that one cycle of BEP chemotherapy worked as well as two in preventing the cancer from returning. In comparison, cancer returns in about half of all men with this type of cancer who have no chemotherapy following surgery.

Did the treatments have side effects?

Many participants had side effects but most often they were mild and/or did not last long. Four out of 10 participants had at least one side effect that was classed as more severe, even though in most cases the patient was unaware there was a problem. These included a drop

in white blood cells and blood clotting cells (platelets) or a high temperature typically lasting just a few days. A small number of people had longer term side effects but severe effects were relatively rare (reported by 3 out of 100 participants).

What do these results mean?

The trial team concluded that one cycle of BEP had similar outcomes as two cycles despite using a much lower total dose of BEP chemotherapy.

The results confirm that one cycle of BEP should become a standard treatment for people with early stage testicular cancer when there is a high risk of the cancer returning after the testicle containing the cancer has been removed.

We would like to thank you for taking part in the 111 trial. Without the contribution of people like you, this study would not have been possible.

If you have any questions about these results, please discuss them with your consultant.

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The Chief Investigator is Professor Michael Cullen of Queen Elizabeth Hospital, Birmingham. The 111 trial is coordinated by the Clinical Trial and Statistics Unit at the Institute of Cancer Research (ICR-CTSU).

