

CALIBER

First results of CALIBER: A phase II randomised feasibility study of Chemoresection and surgical management in Low risk non muscle invasive Bladder cancer

You previously agreed to take part in a research study called CALIBER, a study in low risk bladder cancer which came back after previous treatment

CALIBER aimed to find out whether using chemotherapy inside the bladder (chemoresection) might allow people to avoid surgery if their low risk bladder cancer came back after being treated (recurred). To measure how well chemoresection worked we looked at whether there was any cancer left in the bladder three months after treatment.

In August 2017 a group of independent experts reviewed data collected so far. They advised that enough information was available to determine the results of the study and that no further participants were required.

We stopped inviting new patients to join CALIBER in September 2017. In total 82 people joined the study.

The first results of CALIBER study are now available and are described below.

Background

When you consented to take part in CALIBER you were assigned to one of the following treatment groups:

- **Group 1: Surgical management** – people in this group received the surgery they would have had if they had not joined the study.
- **Group 2: Chemoresection** – people in this group were given mitomycin C chemotherapy in their bladder once a week for 4 weeks and did not have surgery.

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 will be 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 will not be identified personally in any of the presentations or publications.

The results:

Participation in the study

82 patients joined CALIBER between January 2015 and September 2017

- 28 patients were in the surgical management group
- 54 patients were in the chemoresection group

Patients from 24 NHS hospitals across the UK joined the study.

How well did chemoresection work?

We found that 3 months after treatment:

- Eight out of ten patients who had surgical management had no cancer in their bladder
- Four out of ten patients who had chemoresection had no cancer in their bladder

This meant that chemoresection using mitomycin C did not work for as many people as we had hoped. Everyone who still had bladder cancer at this check up had surgery to treat it.

Did the treatments have side effects?

We found that 4 out of 20 people in the surgery group and 3 out of 20 people in the chemoresection group had side effects which needed treatment.

The most common side effect requiring treatment was bladder infection. Three people in the surgical group had a bladder infection. No one in the chemoresection group had a bladder infection.

The second most common side effect requiring treatment was blood in the urine. Two people in the surgical management group and one person in the chemoresection group had treatment for blood in their urine.

No one in the study had severe side effects as a result of their treatment.

What do these results mean?

These initial results show that chemoresection using mitomycin C is a safe treatment with few side effects and does help some people avoid surgery. However it does not treat low risk bladder cancer as well as surgery. Further research is required to determine whether using higher doses or different types of chemotherapy in the bladder would work better.

This is an important scientific finding. Although the study has not led directly to a new treatment that is better than the current surgical treatment, this was not known before. Your involvement has made this possible and this finding will help researchers design new studies in the future.

What will happen now?

Participants in the study agreed to donate a small sample of tissue left over from their bladder cancer surgery for laboratory research. We are collecting these samples from participating hospitals and will conduct analyses to help us understand how best to treat bladder cancer in the future.

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

If you have any questions about the results of CALIBER, please discuss this information sheet with your consultant.

This study was funded by the NIHR Research for Patient Benefit programme (PB-PG-0712-28112). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

The Chief Investigator is Mr Hugh Mostafid of Royal Surrey County Hospital. CALIBER is coordinated by the Clinical Trial and Statistics Unit at the Institute of Cancer Research (ICR-CTSU).