

CALIBER

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

We have provided you with this leaflet because you took part in a research study called CALIBER, a study in low risk bladder cancer which came back after previous treatment. This study 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 (recurred) after being treated. 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 updated results of CALIBER have now been published in the British Journal of Urology (BJU) International medical journal. We have written this leaflet to summarise these results. We have also added the link to the publication at the end of this document in case you would like to read the results in more detail. The published results describe the two groups of participants and you cannot be identified personally in any of the publications.

Background

After you agreed to take part in CALIBER you joined 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 had mitomycin C chemotherapy in their bladder once a week for 4 weeks and did not have surgery.

Trial participation

82 people joined CALIBER between January 2015 and September 2017

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

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

How well did chemoresection work?

We found that three months after treatment:

- Eight out of ten people who had surgical management had no cancer in their bladder
- Four out of ten people 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?

Very few side effects were reported. The most common side effect was needing to urinate more often than normal. Eight out of 28 people in the surgical management group and nine out of 53 people in the chemoresection group reported this side effect. No one in the study had severe side effects as a result of their treatment.

Participants in both groups reported similar experiences of quality of life and general wellbeing in the questionnaires they completed.

What do these results mean?

These 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 we had hoped. Further research is required to determine whether using higher doses or different types of chemotherapy in the bladder might 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.

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 your contribution, this study would not have been possible and this finding will help researchers design new studies in the future.

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

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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).