



First results of POUT: PeriOperative chemotherapy or sURveillance in upper Tract urothelial cancer

You previously agreed to take part in a clinical trial called POUT, a study in locally advanced upper tract urothelial cancer. POUT aimed to find out whether having chemotherapy following surgery reduced the chance of cancer returning, in comparison to the usual approach of close observation.

POUT originally planned to include 345 people with upper tract urothelial carcinoma. In October 2017 the independent data monitoring committee, a group of independent experts, reviewed data collected throughout the trial. They advised that enough data was available to answer the question of whether immediate chemotherapy reduced the chance of cancer returning and that no further participants were required.

We stopped inviting new patients to join POUT in November 2017. In total, 261 participants joined the study. The decision to close recruitment to the trial early was not because of any concerns about safety.

The first results of POUT are now available and we have written this leaflet to explain them.

Background

When you consented to take part in POUT you were put in one of the following groups:

- **Close observation (standard of care)** – regular check ups following surgery, with further treatment as needed if the cancer returns
- **Chemotherapy** – chemotherapy for 12 weeks, starting within 3 months after surgery

Data from the clinic appointments that you attended since you joined the study have been collected and analysed at the Clinical Trial and Statistics Unit at the Institute of Cancer Research (ICR-CTSU). The results will be presented at international conferences and published in leading medical journals. The results compare the groups of patients and you will not be identified in any of the presentations or publications.

Participation in the trial

261 patients joined POUT between May 2012 and November 2017

- 127 patients were in the close observation group
- 134 patients were in the chemotherapy group

Patients from 57 NHS hospitals across the UK joined the study.

Did chemotherapy reduce the chance of cancer returning?

We found that at 2 years after joining the study:

- 54 out of 100 people who had close observation were alive and free of cancer
- 71 out of 100 people who had chemotherapy were alive and free of cancer

Our best estimate is that the risk of the cancer returning or of dying is reduced by about half when chemotherapy is given within three months after surgery.

Did chemotherapy reduce the chance of cancer spreading to another part of the body?

We found that at 2 years after joining the study:

- 60 out of 100 people who had close observation were alive and the cancer had not spread
- For 74 out of 100 people who had chemotherapy were alive and the cancer had not spread

This means that having chemotherapy, within three months after surgery, reduces the risk of the chance of upper tract urothelial cancer spreading to other areas of the body after surgery by about half.

Did chemotherapy have side effects?

We found that 54 out of 100 people who had chemotherapy experienced a serious symptom or side effect during treatment. However, serious symptoms were also reported during the same time for 15 out of 100 people who had close observation. The most common side effect experienced by people having chemotherapy was a decrease in numbers of white blood cells, which prevents the immune system working as well as it should. The most common symptom experienced by people who had close observation was high blood pressure.

When we include any symptoms and side effects people had following treatment, we found that

- 62 out of 100 people who had chemotherapy experienced a serious symptom or side effect
- 25 out of 100 people who had close observation experienced a serious symptom

This means that people who have chemotherapy are more likely to have serious symptoms or side effects.

What do these results mean?

POUT is the largest clinical trial conducted worldwide of this type of treatment in upper tract urothelial cancer. Based on the results of POUT, we can recommend that every patient in the future who has locally advanced upper tract urothelial cancer should be offered chemotherapy after surgery instead of close observation.

However, because the chemotherapy has to be given within 3 months after surgery, if you did not receive chemotherapy as part of this trial we would not recommend that you receive this chemotherapy now.

What will happen now?

Some POUT participants have only been in the study for a few months. We do not yet know what will happen in the longer term, and so we will continue to collect data about all the participants to see if any other differences emerge. *You do not need to do anything other than continue to attend your hospital appointments.*

We would like to thank you very much for taking part in POUT. Without your contribution this trial would not have been possible.

If you have any questions about the results of POUT, please discuss this information sheet with your consultant, who will be happy to help you.

POUT is funded by Cancer Research UK. The Chief Investigator is Dr Alison Birtle of the Royal Preston Hospital. POUT is coordinated by the Clinical Trial and Statistics Unit at the Institute of Cancer Research (ICR-CTSU).

