



Long Term Results of the POUT trial: PeriOperative chemotherapy or sUrveillance in upper Tract urothelial cancer

Background

You have been given this leaflet because you took part in a clinical trial called POUT, a study in locally advanced upper tract urothelial cancer. This study aimed to find out whether giving a drug treatment (chemotherapy) after surgery to remove the cancer would reduce the chance of it returning. This chemotherapy treatment was compared to the usual approach of close observation following surgery.

The results of POUT were published in 2020 and a leaflet summarising the results was provided to your hospital to give to you at that time. As all participants have now been followed up for a longer period, we have more information to tell us about how well patients did in the longer term. These updated results are summarised here and have also been published in a medical journal. The link to the publication can be found at the end of this leaflet in case you would like to find out more. The results compare the two groups of participants and you cannot be identified in any of the publications.

Treatment groups

After you agreed to take part in POUT you joined one of the following groups:

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

Trial participation

261 people joined POUT between May 2012 and November 2017

- 129 people were in the close observation group
- 132 people were in the chemotherapy group

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

Did chemotherapy reduce the chance of cancer returning?

Five years after joining the study:

- For 45 out of 100 people who had close observation the cancer had not returned
- For 62 out of 100 people who had chemotherapy the cancer had not returned

Chemotherapy after surgery reduces the risk of this type of cancer returning. This finding, over a longer period of monitoring, confirms the initial results from the trial. We also found that, on average, people who had chemotherapy were free from cancer for 18 months longer than those who had close observation.

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

Five years after joining the study:

- 46 out of 100 people who had close observation did not have cancer spread to another part of the body
- 64 out of 100 people who had chemotherapy did not have cancer spread to another part of the body

Chemotherapy after surgery reduces risk of cancer spreading to other areas of the body. People who had chemotherapy were less likely to have their cancer return and spread to another part of their body than those who had close observation. This finding, over a longer period, confirms the initial results of the trial.

Did chemotherapy reduce the chance of dying?

Five years after joining the study:

- 57 out of 100 people who had close observation were alive
- 66 out of 100 people who had chemotherapy were alive

We found that, on average, people who had chemotherapy lived for 11 months longer than those who had close observation. This is the first time we have published the impact of chemotherapy on preventing death as we needed to collect more information to make sure the analysis was reliable.

Did chemotherapy reduce the chance of a second cancer developing in the bladder?

Five years after joining the study:

- 71 out of 100 people who had close observation did not have a second cancer in the bladder
- 69 out of 100 people who had chemotherapy did not have a second cancer in the bladder

There was no difference between the groups in the chance of developing a second cancer in the bladder. This is the first time we have published the impact of chemotherapy on development of second cancer in the bladder as we needed to collect more information to make sure the analysis was reliable.

Side effects updates

We found that serious symptoms reported between 6-24 months after joining the study were similar in the two groups. There was also no difference observed in quality of life reported by our study participants.

What happens next?

The results of the POUT trial have already changed the way that patients with this type of cancer are treated. Chemotherapy after surgery is recommended by the European Association of Urology, who produce international guidelines for cancer treatment. These updated results further support the use of chemotherapy after surgery for upper tract urothelial cancer.

What will happen now?

Some study participants also agreed to donate a small sample of tissue from their cancer surgery as well as blood and urine samples before and after treatment. We have collected these samples from participating hospitals and these will be analysed to help us better understand upper tract urothelial cancer.

If you have questions about the updated results of POUT, please discuss this leaflet with your doctor or nurse.

Thank you for your participation

We would like to thank everyone who took part in POUT. Without your contribution this trial would not have been possible and we would not have been able to improve treatment options for future patients with this type of cancer.

Publication in the Journal of Clinical Oncology

<https://doi.org/10.1200/JCO.23.01659>

The POUT trial is funded by Cancer Research UK. The Chief Investigator is Professor Alison Birtle at Lancashire Teaching Hospitals NHS Foundation Trust. POUT is coordinated by the Clinical Trial and Statistics Unit at the Institute of Cancer Research (ICR-CTSU).

