



## **Results of the POUT trial: PeriOperative chemotherapy or sURveillance in upper Tract urothelial cancer**

### **Background**

We have provided you with 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 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.

We originally planned to include 345 people with upper tract urothelial carcinoma in POUT. Our data monitoring committee, formed of independent experts, met in October 2017. During that meeting they reviewed data about whether cancer had returned for all of the people participating in the trial. They said that no more people needed to join the study. Enough information was available to tell whether immediate chemotherapy reduced the chance of cancer returning. We therefore stopped inviting people to join POUT in November 2017. The decision to stop enrolment was not because of any concerns about the safety of treatment.

The results of POUT have now been published in The Lancet 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 compare the two groups of participants and you cannot be identified personally 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

### **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?**

Three years after joining the study:

- 46 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

Chemotherapy after surgery halves the risk of this type of cancer returning.

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

Three years after joining the study:

- 53 out of 100 people who had close observation were alive and their cancer had not spread
- 71 out of 100 people who had chemotherapy were alive and their cancer had not spread

Chemotherapy after surgery halves the risk of cancer spreading to other areas of the body.

### **Did chemotherapy have side effects?**

We found that 44 out of 100 people who had chemotherapy had a serious symptom or side effect during treatment and up to three months afterwards. However, serious symptoms were also reported during the same time for 4 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. This can prevent the immune system working as well as it should. The most common symptom experienced by people who had close observation was high blood pressure.

People who have chemotherapy are more likely to have serious symptoms or side effects than those who did not. The chemotherapy drugs used in POUT have been used to treat other cancers, such as bladder cancer, for several years. None of the side effects we saw in POUT were different to those seen when this chemotherapy is used to treat other diseases.

### **What do our researchers say?**

The doctor leading the study, Dr Alison Birtle, Consultant Clinical Oncologist at Lancashire Teaching Hospitals NHS Foundation Trust, said:

*“We are very grateful that our participants and the entire uro-oncology community in the UK got behind this study. It is the first to show that there is a real chance for people with upper urinary tract cancer to stay free of their disease for much longer. This type of cancer has always been forgotten and to be able to deliver this, a study that everyone said was impossible, to benefit patients is a privilege.”*

### **What happens next?**

POUT is the largest clinical trial conducted worldwide in upper tract urothelial cancer. Because of these results, we have recommended that every patient with locally advanced upper tract urothelial cancer should be offered chemotherapy after surgery in future, rather than close observation.

Because the chemotherapy has to be given within 3 months after surgery, if you were not in the chemotherapy group in POUT we would not recommend that you receive this treatment at this stage. Instead please continue to attend your appointments at your hospital. If you have any concerns please speak to your doctor or nurse.

### **What will happen now?**

We hope that the results of POUT will lead to a change in treatment for all patients with upper tract urothelial cancer in future. However we plan to continue to collect information about all those who joined the study to see if any other differences emerge. You do not need to do anything to contribute to this other than continue to attend your medical appointments as normal.

We would like to thank you very much for taking 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 locally advanced upper tract urothelial cancer.

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

### **Publication in The Lancet medical journal**

[https://doi.org/10.1016/S0140-6736\(20\)30415-3](https://doi.org/10.1016/S0140-6736(20)30415-3)

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The Chief Investigator is Dr 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).

