

Results of the RAIDER Trial: A Randomised phase II trial of Adaptive Image guided standard or Dose Escalated tumour boost Radiotherapy in the treatment of transitional cell carcinoma of the bladder.

#### **Background**

## Standard radiotherapy

Radiotherapy uses targeted beams of high strength x-rays to kill cancer cells. Because radiotherapy can also damage non-cancer cells, the treatment is carefully planned by doctors and physicists so that only your bladder and a small border surrounding it is treated with the highest radiotherapy dose.

Each person would usually have one radiotherapy treatment plan designed for them based on a CT scan taken a few weeks before treatment. The bladder can move within the body depending on how full it is and because of where it is in relation to the bowel. It is important that the radiotherapy does not miss any of the bladder tumour because of this movement, so a safety margin is added around the bladder on the radiotherapy treatment plan.

#### Adaptive radiotherapy

RAIDER aimed to find out whether it was possible to give people adaptive radiotherapy. This used three treatment plans (small, medium and large) rather than one. The plan that best fitted the size of the bladder was then used for each radiotherapy treatment.

## Tumour focused and boost radiotherapy

We also wanted to find out whether it was possible to focus the highest dose of radiotherapy on the bladder tumour while giving a lower dose to the rest of the bladder. Additionally, we looked at whether it was possible to safely increase the dose of radiotherapy focused on the bladder cancer – a tumour boost.

We wanted to check that side effects of giving tumour boost radiotherapy were similar to those experienced by people having standard radiotherapy.

#### Results

The results of RAIDER have now been published in a medical journal called European Urology. A link to the publication and a visual summary of the results is provided at the end of this leaflet.

# **Treatment groups**

After agreeing to take part in RAIDER, participants joined one of the following groups:

- **Standard radiotherapy** used one radiotherapy plan, giving the whole bladder the same standard radiotherapy dose each time.
- Adaptive tumour focused radiotherapy used small, medium and large plans with the standard radiotherapy dose targeted at the tumour. The rest of the bladder received a lower dose than normal.
- Adaptive tumour boost radiotherapy used small, medium and large plans with a higher than normal dose of radiotherapy targeted at the tumour. The rest of the bladder received a lower dose than normal.

#### **Trial participation**

345 people joined RAIDER between 21st October 2015 and 18th March 2020

- 91 people had standard radiotherapy.
- **94** people had **adaptive tumour focused** radiotherapy.
- **147** people had **adaptive tumour boost** radiotherapy.

A further 13 people didn't have RAIDER treatment as they either changed their mind about taking part, or they were not well enough.

People joined the study from 43 NHS hospitals across the UK, four hospitals in Australia and two hospitals in New Zealand.

## Were there any serious side effects of bladder radiotherapy?

We wanted to find out if people had serious side effects that needed treatment between six and eighteen months after radiotherapy. This is because side effects can develop some time after radiotherapy is finished. These are called serious late side effects.

- One person in the standard radiotherapy group had severe bladder irritation (cystitis).
- One person in the **adaptive tumour focused** group needed treatment to clear a blockage that was preventing them from passing urine.
- One person who had adaptive tumour boost radiotherapy had blood in their urine which needed to be treated at hospital.

#### What were the other side effects?

The main radiotherapy side effects were diarrhoea, difficulty urinating or needing to urinate more often. Most peoples' side effects were worst at the end of radiotherapy but improved after about three months and then they felt similar to before they had treatment.

#### How well did the treatment work?

- 13 out of every 20 people who had either **standard** radiotherapy or **adaptive tumour focused** radiotherapy had no cancer in their bladder two years after treatment.
- 15 out of every 20 people who had **adaptive tumour boost** radiotherapy had no cancer in their bladder two years after treatment.
- 15 out of every 20 people who had either **standard** radiotherapy or **adaptive tumour focused** radiotherapy were alive two years after treatment.

• 16 out of every 20 people who had **adaptive tumour boost** radiotherapy were alive two years after treatment.

More people in the adaptive tumour boost radiotherapy group were alive after two years than in the other two groups. This difference was small and larger clinical trials are needed to confirm that this was due to treatment rather than chance.

## What happens next?

We will continue to collect information about people who joined the study until five years after everyone finished treatment to see if any other differences emerge.

Some people also agreed to donate samples taken at the time their cancer was diagnosed. We have collected these samples from UK hospitals. These will be analysed to help us better understand bladder cancer.

We would like to thank everyone who took part in the RAIDER trial. Without people choosing to take part this trial would not have been possible, and we would not have been able to make progress in improving treatment for future patients with bladder cancer.

# Publication in the European Urology

https://www.europeanurology.com/article/S0302-2838%2824%2902596-X/fulltext

The RAIDER trial is funded by Cancer Research UK. The Chief Investigator is Professor Robert Huddart at The Royal Marsden Hospital NHS Foundation Trust. RAIDER is coordinated by the Clinical Trial and Statistics Unit at the Institute of Cancer Research (ICR-CTSU).





# Are new radiotherapy techniques safe for bladder cancer treatment?



Standard bladder radiotherapy uses one plan, using a scan from before treatment, giving the whole bladder the same radiotherapy dose



Adaptive radiotherapy uses small, medium and large plans and the highest radiotherapy dose can be focused on the tumour



A tumour boost with a higher radiotherapy dose than normal can also be given

345 people took part in RAIDER from 49 hospitals in the UK, Australia and New Zealand



91 people had standard bladder radiotherapy

94 people had adaptive tumour focused radiotherapy





147 people had adaptive tumour boost radiotherapy



2+ years of data was collected about each participant





One participant in each group had a serious side effect caused by radiotherapy





Adaptive tumour boost bladder cancer radiotherapy is safe, with similar side effects to standard bladder radiotherapy