Conventional or Hypofractionated High Dose Intensity Modulated Radiotherapy for Prostate Cancer

The CHHiP trial

Results for prostate cancer control and side effects at 5 years after completion of radiotherapy

A summary in plain English

The aim of the CHHiP trial is to improve the effectiveness of radiotherapy treatment for men with prostate cancer and at the same time reduce the number of visits patients need to make. We wanted to achieve this by seeing if we could give radiotherapy over 4 weeks instead of 7.5 weeks and give patients more radiotherapy at each visit.

CHHiP used a technique to give radiotherapy called conformal intensity modulated radiotherapy (IMRT), this meant that the radiation beams were carefully shaped for individual patients and could be given at higher doses at each fraction over fewer visits to hospital.

3216 people joined the study between October 2002 and June 2011. The study was conducted in 42 radiotherapy hospitals in the UK, Ireland, Switzerland and New Zealand.

The main results for prostate cancer control and side effects at 5 years after completion of radiotherapy in the study are now available and are explained here.

Glossary:
- **Gray** – The amount of radiotherapy people received is measured in ‘Grays’ (or Gy for short).
- **Fraction** – Radiotherapy was given in doses known as ‘fractions’ and people received one fraction at each visit to hospital for radiotherapy treatment.
- **Prostate Specific Antigen (PSA)** – A protein produced by prostate cells. Doctors monitor the level of this protein in the blood.
Background

People who consented to take part in the CHHiP trial were allocated at random to one of the following radiotherapy treatment groups:

- **Group 1** - Standard radiotherapy of 74 Gray given in 37 two Gray fractions over 7.5 weeks
- **Group 2** - Radiotherapy of 60 Gray given in 20 three Gray fractions over 4 weeks
- **Group 3** - Radiotherapy of 57 Gray given in 19 three Gray fractions over 3.8 weeks

Data from the clinic appointments that people kindly attended over a number of years have been collected and analysed at the Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU). The results have been published in a leading medical journal so that doctors around the world can be made aware of the findings. The results compare the groups of patients.

The results:

Prostate cancer control

After an average follow up of 5 years after radiotherapy, control of prostate cancer is similar between the three groups.

At 5 years after radiotherapy the proportion of patients who were free of disease according to routine prostate specific antigen (PSA) measurements and clinical assessments was:

- About 88 of 100 (88.3%) patients treated in **Group 1**
- About 91 of 100 (90.6%) patients treated in **Group 2**
- About 86 of 100 (85.9%) patients treated in **Group 3**

Side effects

The safety data collected during the study have shown that safety and side effects in each group were similar and low.

By 5 years moderate or severe bowel side effects (often temporary) had been reported at some time in:

- About 14 of 100 (13.7%) patients treated in **Group 1**
- About 12 of 100 (11.9%) patients treated in **Group 2**
- About 11 of 100 (11.3%) patients treated in **Group 3**

By 5 years moderate or severe bladder side effects (often temporary) had been reported at some time in:

- About 9 of 100 (9.1%) patients treated in **Group 1**
- About 12 of 100 (11.7%) patients treated in **Group 2**
- About 7 of 100 (6.6%) patients treated in **Group 3**
When looking at side effects that remained at 5 years, moderate or severe bowel side effects were found in:

About 1 of 100 (1.3%) patients treated in **Group 1**
About 2 of 100 (2.3%) patients treated in **Group 2**
About 2 of 100 (2.0%) patients treated in **Group 3**

When looking at side effects that remained at 5 years, moderate or severe bladder side effects were found in:

About 2 of 100 (1.7%) patients treated in **Group 1**
About 2 of 100 (1.8%) patients treated in **Group 2**
About 2 of 100 (1.8%) patients treated in **Group 3**

The results have shown that radiotherapy delivered in fewer fractions but higher doses over 4 weeks is as effective as the standard treatment using a larger number of lower doses for treating prostate cancer. The results were better than we had predicted before the trial started for all groups treated. Side effects are similar between the 3 different groups. All groups have a reduced level of side effects and better disease control compared with men treated in a previous national UK trial (the RT01 study) due to the high quality “state of the art” radiotherapy techniques used in the CHHiP trial.

Following these results, the group that organised the study recommend that the 4 week schedule of radiotherapy should become standard radiotherapy treatment for men with localised prostate cancer. It is both more convenient for men and less expensive than the older standard treatment given over 7.5 weeks.

**What will happen now?**

We will continue follow up of all the men who entered the CHHiP trial so that we are able to assess disease control and side effects at longer than 5 years after radiotherapy. We hope to report data on 5 year quality of life outcomes later in 2016.

Many men in the study agreed to donate a small sample of tissue left over from their prostate cancer diagnosis for laboratory research. We have collected these samples from participating hospitals and have begun molecular tests (which will look at proteins and genes) to help us improve understanding of the biology underlying radiotherapy treatment for prostate tumours.

**Thank you** to all the men taking part in CHHiP – without their contribution, this trial would not have been possible.

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

*The CHHiP trial has received funding from Cancer Research UK and the Department of Health. The Chief Investigator is Professor David Dearnaley of the Institute of Cancer Research and Royal Marsden Hospital. CHHiP is coordinated by the Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU).*