



RADICALS-RT

Radiotherapy and Androgen Deprivation In Combination After Local Surgery A randomised controlled trial in prostate cancer.

November 2011

Welcome to the November 2011 edition of the **RADICALS-RT** newsletter. The new version of the **RADICALS protocol (version 4.0)** has been approved and is now in use. The trial team would like to ask that you ensure that the new versions of the protocol, Patient Information sheets and Consent Forms are now in use, and that you return the Amendment Confirmation to the CTU. If you have any questions regarding the new protocol, or anything you would like to see in either newsletter, let us know at radicals@ctu.mrc.ac.uk.

Quality of Life Questionnaires

The Quality of Life assessment is one of the most important assessments in RADICALS-RT as there is currently limited patient-reported data on symptoms and morbidities associated with treatments after radical prostatectomy. We would like to encourage all RADICALS-RT patients and centres to contribute to this sub-study as much as possible. Please remember to ask all RADICALS-RT patients to complete the Quality of Life Questionnaire at baseline, 1 year, 5 years and 10 years. Quality of life is a very important outcome measure for the trial so complete data collection is crucial. RADICALS-HD only patients **do not** need to complete any questionnaires.

Further information on the Quality of Life questionnaires can be found in Appendix A VI of the protocol, or feel free to contact the trial team at radicals@ctu.mrc.ac.uk.

Introducing our Surgical Champions



We are very pleased to introduce you to the two members of the RADICALS Trial Management Group known as our **Surgical Champions**. Mr Raj Persad is a Consultant Urologist at the Bristol Royal Infirmary and Southmead Hospital. Mr Bill Cross is a Consultant Urologist at the Leeds Teaching Hospitals NHS Trust. Both Raj and Bill have been very busy visiting RADICALS centres up and down the nation and talking to people about participating in the RADICALS trial from a surgeon's perspective. Many centres have

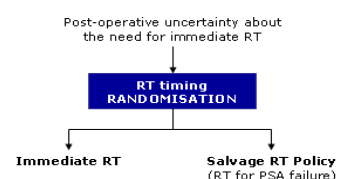
found it very useful to speak to Raj and Bill. They have suggested ways of flagging up RADICALS to patient's in your surgical clinics, recommended ways of restructuring patient pathways so that eligible patients can be offered the trial and share their experiences of recruiting to the trial as surgeons.

If you think it would be helpful for one of our Surgical Champions to speak to your centre, please contact radicals@ctu.mrc.ac.uk.



Timing between Surgery and Randomisation

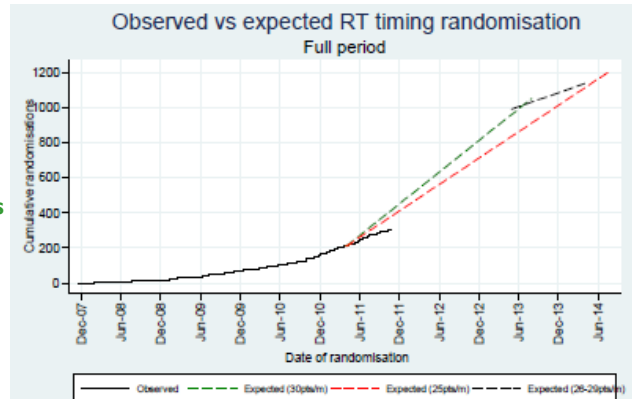
The RADICALS trial is designed to be flexible and available to patients with non-metastatic adenocarcinoma of the prostate that have undergone radical prostatectomy surgery. Prospective patients have ideally up to 22 weeks from their surgery to be randomised into the trial, and 26 weeks from their surgery to start trial treatment if they are allocated to the Early Radiotherapy arm. This allows time for patients to recover from surgery before they are randomised into the trial and before trial treatment begins. It's useful to remember these timelines when looking for potential patients.



RADICALS-RT Accrual

While we have been pleased to report that the accrual rates to RADICALS-RT has been promising, over the summer we have suffered a slight dip in the number of patients joining the randomisation each month, but we're confident that we can turn this around. There are now **314** patients in RADICALS-RT, with an average of **15** patients per month joining RADICALS-RT. The top ten centres recruiting to RADICALS-RT are listed below:

Centre	Pts	Centre	Pts
Southmead Hospital	23	Royal Gwent Hospital	10
Mid-Yorkshire Hospitals	18	York District Hospital	10
Mount Vernon Hospital	15	St. James University Hospital	9
Bradford Royal Infirmary	11	Birmingham Heartlands Hospital	8
Maidstone Hospital	11	Guy's Hospital	8



RADICALS-RT Recruitment Aids

The trial team at the CTU are pleased to see that the RADICALS 'Green Booklet' and the Patient Information DVDs are proving to be a useful and popular way of promoting the RADICALS trial to patients. If you require any more of these versatile items, please contact the trials team or alternatively you can visit our website (www.radicals-trial.org) which has both the DVD and Green Booklet content online.



New CRF Updates

The trial team at the MRC CTU have been working on tweaking the current RADICALS CRF's so that they remain easy to complete while enhancing the quality of the data that they are able to capture. A brief overview of the changes are listed below:

RT Timing Randomisation Form (CRF 3):

- The CRF has been updated to allow a more efficient method of identifying patients that also intend to be randomised into RADICALS-HD. This includes which RADICALS-HD arms the patient will be randomised between (if known or at all), as well as updated hormone therapy options.
- New questions have been added to the form to determine any hormone therapy for patients not joining RADICALS-HD, and to confirm whether the baseline Quality of Life form has been completed.

The trial team at the MRC CTU will be in contact with centres regarding the new CRF versions in the coming weeks.

RANDOMISATION LINE 020 7670 4777

(Mon –Fri 9am-5pm)

For SAE reporting please refer to the flow diagram in section 11 of the protocol

SAE fax: 020 7670 4818

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****Please note that the MRC CTU Randomisation line will be closed for Christmas between 5pm on Friday 23rd December 2011 until 9am on Tuesday 3rd January 2012****