



RADICALS-HD

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

November 2011

Welcome to the November 2011 edition of the **RADICALS-HD** 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.

RADICALS-HD now has 1000 patients

We are very pleased to report that we have had very encouraging accrual rates in recent months with a record breaking **47** patients joining RADICALS-HD in August 2011.

A huge milestone has been reached at the beginning of September 2011; 1000 patients have now joined the RADICALS-HD comparison. Western General Hospital in Edinburgh randomised the 1000th patient into the comparison. Thanks to them and all RADICALS centres for the hard work and support for the trial which means that we are now halfway to completing recruitment to RADICALS-HD.

We would like to thank you all for your hard work and support in helping make RADICALS a success. We look forward to seeing accrual rates continue to improve each month!

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:

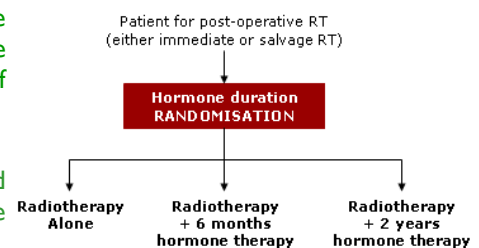
Baseline Information Form (CRF 1a):

- The question "When is radiotherapy indicated?" has been removed and replaced with "What are the plans for radiotherapy timing?", while the wording of the options has been updated for clarity.
- A new question confirming the randomisation the patient will be joining has been added, which we hope will also help clarify which Randomisation Form to complete.

Hormone Duration Randomisation Alone form (CRF 4):

- The Planned RT Schedule options have been updated with a third option of 'Other'. This allows RT schedules that may differ from the standard practice to be accurately captured in the trial data.
- The choices of hormone therapy have been updated to include examples of each type, while the LHRH option has been split into LHRH Agonists and LHRH Antagonists.

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



MRC On The Road

We would like to thank everyone that came to the MRC Joint GU Trials Meeting in London at our new home Aviation House in July 2011. The RADICALS trial team also had a great response at the GU Trials Meeting in Cardiff in October 2011. The team hopes to be on the road again throughout 2012 with trials meetings around the country, and we hope as many of you can make it to a meeting near you as possible.

International Collaborations for RADICALS

We are pleased to be able to announce that RADICALS is now open and recruiting in the UK, Canada, Ireland and Denmark, and we hope to be opening in several new centres in the near future.

- University Hospital Galway in Ireland has now opened and been recruiting since May 2011.
- Rigshospitalet in Copenhagen and Herlev University Hospital, both in Denmark, are also now open and recruiting.

We would like to welcome all our new colleagues to RADICALS and wish them every success in recruiting to this important trial.

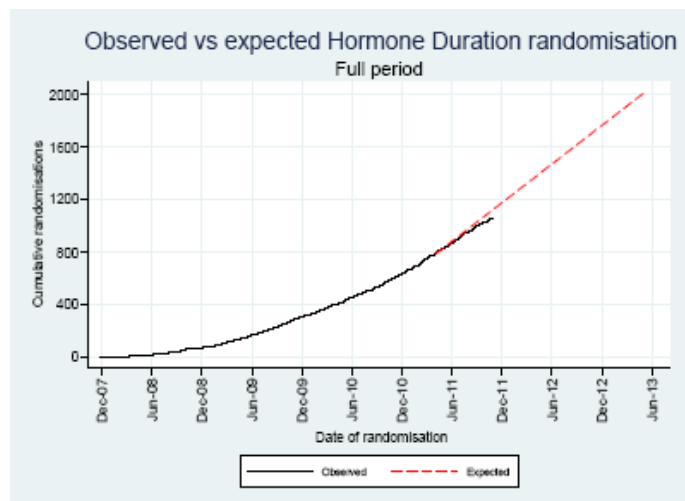
RADICALS Website: www.radicals-trial.org

The trial team at the CTU are pleased to see that the RADICALS Patient Information DVDs are proving to be a useful and popular way of promoting the RADICALS trial to patients. All the content from the DVDs is available on the RADICALS Trial website and hosted on YouTube. If you require any more of the DVDs please contact the trial team at the MRC who will be happy to send some out.

RADICALS Centres and Randomisations

We are really pleased to report that the number of RADICALS sites open in the UK and Canada has increased to **127!** Below is a list of the Top 10 recruiting centres up to 31st October 2011.

Centre	Patients
Guy's Hospital (London)	61
Mount Vernon Hospital (Middlesex)	55
Princess Margaret Hospital (Toronto)	52
Cancer Care Manitoba	41
Centre Hospitalier Uni. de Sherbrooke	40
Christie Hospital (Manchester)	30
Ottawa Health Research Institute	30
Glan Clwyd	30
Stepping Hill Hospital	29
Royal Marsden Hospital (Sutton)	26



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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MRC contacts for the RADICALS trial

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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****