



# RADICALS-HD

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

February 2011

Welcome to the February 2011 edition of the **RADICALS** newsletter. You will have noticed that we now have a newsletter for RADICALS-HD and one for RADICALS-RT. We can now fit even more news about each randomisation into the newsletters. If you have anything you would like to see in either newsletter, let us know at [radicals@ctu.mrc.ac.uk](mailto:radicals@ctu.mrc.ac.uk).

### RADICALS accrual continues to improve!

We are very pleased to report that we have had very encouraging accrual rates in recent months with record numbers of patients joining the trial each month. 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!

### ASTRO Update: First results from RTOG 9601

At the ASTRO annual meeting last November, Bill Shipley presented the first outcome data from RTOG 9601. From 1998-2003, 771 men with PSA failure after radical prostatectomy were randomised to bicalutamide 150mg daily versus placebo, given for 2 years, during and after salvage RT to the prostate bed. The main outcomes, reported at 7 years, show an advantage for bicalutamide in terms of biochemical control and distant metastasis with a trend towards an overall survival benefit (see table). Two years of bicalutamide was not associated with significant cardiac toxicity (grade III/IV toxicity 3% versus 2%).

	Salvage RT + bicalutamide	Salvage RT + placebo	
Freedom from PSA failure	57%	40%	P<0.0001
Freedom from metastases	93%	87%	P<0.04
Overall survival	91%	86%	

What are the take-home messages from this trial?

- First, salvage radiotherapy is a good treatment. Even among men with Gleason 8-10 cancers, the 7-year biochemical control was 26% for radiation alone. Men with PSA failure after surgery should not be denied salvage RT just because they have high-risk features.
- Second, the addition of hormone therapy may improve the outcome compared with salvage RT alone. These data strengthen the rationale for RADICALS-HD.

If you are convinced by these data that hormonal therapy is indicated in addition to salvage RT, then you may want to enter men into the 6 versus 24 months comparison in RADICALS-HD, to see whether the same benefit can be obtained with shorter course hormone therapy.

If, like me, you remain uncertain of the role of hormone therapy in this setting, you may want to enter men into the three-way comparison of 0 versus 6 versus 24 months in RADICALS-HD. This three-way comparison is most efficient for the trial. The greater the proportion of men entered into the three-way comparison, the fewer men that will be needed to complete accrual.

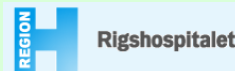
*Chris Parker, RADICALS Chief Investigator*

## New International Collaborations for RADICALS

RADICALS is an international trial which is open and recruiting in the UK and throughout Canada. We are very pleased that our international collaborations are now being extended to Denmark, Ireland and the United States.

- Rigshospitalet in Copenhagen, Denmark, with Dr Peter Meidahl as Principal Investigator, will begin recruitment to RADICALS this month. Further Danish hospitals intend to join soon.
- University Hospital Galway in Ireland has now obtained all the necessary approvals for RADICALS. With Mr Garrett Durkan as Principal Investigator, recruitment is due to begin very soon.

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](http://www.radicals-trial.org)

Don't forget to check out the RADICALS website for useful documents, information videos, latest news and centre-specific accrual figures which are updated monthly.

## 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 **116!**

Centre	Patients
Mount Vernon Hospital (Middlesex)	54
Guy's Hospital (London)	45
Princess Margaret Hospital (Toronto)	44
Cancer Care Manitoba	32
Centre Hospitalier Uni. de Sherbrooke	28
Royal Marsden Hospital (Sutton)	25
Christie Hospital (Manchester)	24
Maidstone Hospital	23
Pinderfields General Hospital (Wakefield)	23
Kent and Canterbury Hospital	23

Below is a list of the Top 10 recruiting centres up to 31<sup>st</sup> January 2011.

If your centre would like to join RADICALS, please email

**radicals@ctu.mrc.ac.uk**

or call

**020 7670 4844**

to request all the necessary documents to make local R&D applications and the accreditation documents that need to be completed and returned to us. If patients are having radiotherapy at your centre, accreditation includes a simple radiotherapy quality assurance

Contact us with any questions you may have about opening your centre to RADICALS recruitment.

### 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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