

RADICALS

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

February 2010

Welcome to the February 2010 edition of the **RADICALS** newsletter. The number of **RADICALS** sites open in the UK and Canada has increased to **88!**

409 patients have joined one or both of the trial's randomisations. Thank you for all your hard work and support in getting your centres open and recruiting patients. We hope you can continue the hard work which will be needed to help us reach our target of approximately 4000 patients.

New RADICALS Protocol (V3.0)

Version 3.0 of the RADICALS protocol has been approved and sent out to all open sites and also to those sites that are looking to join the trial. The first point of contact at each site should have received a hard bound copy of the new protocol. The **two main changes** clarify the eligibility criteria and uncouple the randomisations to make recruitment **simpler for you**:

(1) Uncoupling of randomisations

The randomisations are uncoupled so that patients considering the Radiotherapy Timing Randomisation do not have to consent to the Hormone Duration Randomisation at the same time. This allows you to discuss RADICALS with your patients in stages, avoiding that overwhelming feeling of too many decisions to make at one time AND it also allows patients to join the trial whether they have already made a decision about their use of hormones or not. We still hope that patients joining the Radiotherapy Timing Randomisation will join the Hormone Duration Randomisation if and when they decide to have radiotherapy.

(2) Clarification of the eligibility criteria

The eligibility criteria for the Radiotherapy Timing Randomisation are made explicit to help you to identify eligible patients for the trial and discuss them at you MDT meetings.

We have asked for a fax confirmation acknowledging the receipt and acceptance of the new version of the protocol. A template for the acknowledgement is attached to the accompanying email. So if you have not faxed this through as yet, please do so ASAP, to **020 7670 4818**.

RADICALS Videos out now!

The new RADICALS patient information videos have been sent out to every open site as DVDs. These videos can complement the patient information sheets, and may help the patients digest the information better. There are separate videos for each randomisation.

We would greatly appreciate your thoughts on the DVDs: specifically the content and experience in using them. If you have any comments please email us at radicals@ctu.mrc.ac.uk. Although we would encourage you to ask for the DVDs to be returned you can contact us if you require more.

All the clips are also available online at:

www.youtube.com/radicalstrial



RTOG Post-operative radiotherapy guidelines

The RTOG have just published consensus guidelines for localising the prostate bed for post-operative radiotherapy. Their guidelines are consistent with the RADICALS trial. You can find the details in the "Red Journal" (Int. J. Radiation Oncology Biol. Phys., Vol. 76, No. 2, pp. 361–368, 2010. PMID: 19394158).

RADICALS Quality of Life Questionnaires

Over recent months we have received a number of quality of life forms for patients not participating in the Radiotherapy Timing Randomisation.

Patients are **only** required to complete the **quality of life forms** if they are entering the **Radiotherapy Timing Randomisation**.

Please refer to section 7.4.1 of the protocol.

RADICALS Open Teleconference

We are planning an 'open teleconference' next month for staff at RADICALS centres to dial into and discuss any issues you might have in the trial. The proposed date for this is **Friday 19th March at 4pm**. More details of the teleconference will be sent out by email soon.

RADICALS Centres and Randomisations

There are 78 UK centres open to RADICALS recruitment and 9 centres in Canada. Below is a list of the Top 10 recruiting centres up to January 2010.

Centre	Patients
Mount Vernon Hospital (Middlesex)	37
Princess Margaret Hospital (Toronto)	35
Royal Marsden Hospital (Sutton)	20
Christie Hospital (Manchester)	18
Pinderfields General Hospital (Wakefield)	17
Guy's Hospital (London)	16
St James University Hospital (Leeds)	15
Maidstone Hospital	14
Stepping Hill Hospital (Stockport)	14
Mayday Hospital (Croydon)	13

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 (RTQA) exercise (unless your site has participated in certain other prostate cancer trials requiring RTQA).

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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