

RADICALS

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

Update March 2016

Reporting Disease Events: Important Trial Definitions

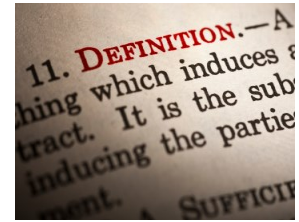
When reporting disease events for all RADICALS patients please ensure the following definitions are used:

Biochemical progression: EITHER 2 consecutive rises in PSA and final PSA >0.1ng/ml OR 3 consecutive rises in PSA.

This definition should be used to trigger deferred RT and when reporting biochemical progression post RT.

Castrate resistant disease progression: 2 consecutive rising PSA values in the presence of a castrate level of testosterone.

If these definitions have not been used please complete a **Disease Event Form** to report the date of progression retrospectively; please then record this type of progression as “previously reported” on subsequent Follow-Up Forms.



New CRFs



We are trying to improve the way we collect information. New versions of the following CRFs are now available via the website: CRF3 RT Timing Randomisation Form, CRF6 Follow-up Form, CRF7 Disease Event Form and Co-Enrolment Form. We also have a new CRF: the Additional Treatment Update Form.

Some important changes:

- :: Please use **CRF6 Follow-up Form** to tell us about hormone therapy given as per protocol (RADICALS-HD) or as part of standard-of-care (RADICALS-RT).
- :: For any hormone treatment given for relapse post radiotherapy, please complete an **Additional Treatment Update Form**; this form should also be used to collect information about any other treatments given from the point of progression.
- :: Please use the updated **Co-Enrolment Form** to let us know about patients participating in any other interventional trials.

We have also updated our **CRF Completion Guidelines** which can be found on our trial website. We welcome your feedback, please do let us know what you think!

Data Queries & Data Chase



We are planning to send data queries and chase outstanding forms on **25th April 2016**. In preparation for the upcoming Independent Data Monitoring Committee meeting, we would be very grateful if you could respond to the queries and return them to us as soon as possible so that we can process the data.

Recognising Achievement & Sharing Good Practices



We would like to thank the team at the Radiotherapy Department at **St James's University Hospital in Leeds** for all their efforts in the trial so far. They have treated 92 patients from St James as well as patients from the following peripheral hospitals: Airedale General Hospital, Bradford Royal Infirmary, Pinderfields Hospital and York District Hospital. Thank you for your contribution and keep up the good work!

Can electronic records help data collection?

The team at **Guy's and St Thomas'** have developed an electronic assessment for the RADICALS trial which is proving a quick and reliable way of ensuring all necessary information is obtained at each visit. All oncology notes are electronic and the research team write a prompt in the electronic notes when a trial patient is due asking the doctor to complete the assessment. The prompt includes what trial follow up it is and when next trial visit is due. The assessment is completed as an electronic form in the patient's notes. We hear it works well for them, maybe it would work well at your site? We are always keen to hear about tips and examples of innovation, please get in touch and we will share them next time!



Accrual Update



RADICALS-RT is still recruiting with already a fantastic **1216** patients! Discussions are still ongoing as to when to close to the trial, so please continue your efforts in supporting this very important study.

A big thank you to all those who have been busy recruiting especially **Herlev University Hospital** in Denmark who recruited a fantastic 6 patients, and **Bradford Royal Infirmary** who recruited 5 patients in the last 3 months!

Co-Enrolment with Add-Aspirin

Does adding aspirin to standard therapy improve outcomes?

This is the question being addressed by the Add-Aspirin trial. Co-enrolment in RADICALS and Add-Aspirin is possible but we ask that you refer to the following guidance if patients at your centre are interested in both trials.



:: In patients eligible for both trials we suggest that RADICALS-RT is discussed first and then co-enrolment with Add-Aspirin is considered.

:: All N0 patients in RADICALS-RT are potentially eligible for co-enrolment in Add-Aspirin at the point that they have radiotherapy – either immediate or deferred.

Randomisation

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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