

Please complete this form **after randomising the patient** and photocopy. Send the original to your trials unit **with a copy of the pathology report:**

MRC: RADICALS Data Manager, MRC Clinical Trials Unit, Aviation House, 125 Kingsway, London, WC2B 6NH

NCIC CTG: Clinical Trials Assistant, NCIC CTG, Queen's University, 10 Stuart Street, Kingston, Ontario, K7L 3N6, Canada

Patient's initials
F M L

Date of birth
d m y

MRC Patient ID No.

NCIC CTG Patient ID No.

Hospital No. Responsible investigator Institution

Prostate cancer history

1 Date of first diagnosis of PCa
d m y

2 PSA at diagnosis ng/ml or µg/l

3 Date of PSA test at diagnosis
d m y

Radical prostatectomy details

4 Surgeon

5 Surgery Hospital

6 **Radical Prostatectomy technique**
1 = Open retropubic
2 = Open perineal
3 = Laparoscopic
4 = Robotic
9 = Not known

Pathology details

Please attach pathology report to CRF when returning form

7 Pathologist

8 Pathology reference number

9 **Node dissection performed?**
0 = No
1 = Yes, nodes negative
2 = Yes, nodes positive

10 **T** **Pathological T Stage and substage**

Please use the TNM classification 2002 (see Appendix A)

11 **Is the pathology report attached to this CRF?**
1 = Yes
0 = No, please specify a reason

Signed by

(only MRC authorised person / NCIC CTG investigator)

Date
d m y

Please complete the following questions from the Charlson Comorbidity Index before or after randomising the patient. Photocopy and send the original immediately to your trials unit: Page 1 of 1

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Patient's initials

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 Date of birth

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 MRC Patient ID No.

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NCIC CTG Patient ID No.

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Hospital No. Responsible investigator Institution

1 Does the patient have any of the following conditions?
 0 = No. Please complete Q2.
 1 = Yes. Please complete Q2-21.

2

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 Date of comorbidity assessment

3 Myocardial infarction
 0 = No
 1 = Yes

4 Congestive heart failure
 0 = No
 1 = Yes

5 Peripheral vascular disease
 0 = No
 1 = Yes

6 Cerebrovascular disease
 0 = No
 1 = Yes

7 Dementia
 0 = No
 1 = Yes

8 Chronic pulmonary disease
 0 = No
 1 = Yes

9 Connective tissue disease
 0 = No
 1 = Yes

10 Ulcer disease
 0 = No
 1 = Yes

11 Mild liver disease
 0 = No
 1 = Yes

12 Diabetes
 0 = No
 1 = Yes

13 Hemiplegia
 0 = No
 1 = Yes

14 Moderate or severe renal disease
 0 = No
 1 = Yes

15 Diabetes with end organ damage
 0 = No
 1 = Yes

16 Any other tumour
 0 = No
 1 = Yes

17 Leukemia
 0 = No
 1 = Yes

18 Lymphoma
 0 = No
 1 = Yes

19 Moderate or severe liver disease
 0 = No
 1 = Yes

20 Metastatic solid tumour
 0 = No
 1 = Yes

21 AIDS Please answer 0 if patient is HIV +ve
 0 = No
 1 = Yes

Signed by

(only MRC authorised person / NCIC CTG investigator)

Date

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Hospital No. Responsible investigator Institution

1 Does the patient meet the eligibility criteria?
 0 = No
 1 = Yes

2 Was the PSA detectable post-operatively?
 0 = No (go to question 4)
 1 = Yes

3 Post-operative PSA value
ng/ml or µg/L

4 PSA assay sensitivity if undetectable
ng/ml or µg/L

5 Date of PSA test
d m y

6 Planned RT schedule
 1 = 52.5Gy in 20 fractions
 2 = 66Gy in 33 fractions
 3 = Other (discuss with MRC CTU or NCIC CTG)

7 Planned RT target
 1 = Prostate bed
 2 = Prostate bed and pelvic lymph nodes

8 Would the patient be joining RADICALS-HD if randomised to Early RT?
 0 = No (Please go to question 9)
 1 = Yes (Please go to question 8)
 2 = Not yet decided (Please go to question 9)

9 Which arms would the patient be randomised between in RADICALS-HD?
 1 = 3-way randomisation: (RT alone) vs. (RT + 6m HT) vs. (RT + 2y HT)
 2 = 2-way randomisation: (RT alone) vs. (RT + 6m HT)
 3 = 2-way randomisation: (RT + 6m HT) vs. (RT + 2y HT)

10 If not joining RADICALS-HD, what hormone treatment would the patient likely receive with radiotherapy?
 0 = None (go to question 11)
 1 = 6 months
 2 = 2 years
 3 = Not yet decided (go to question 11)
 4 = Other duration (please specify) _____

11 Choice of hormone therapy if allocated in RADICALS-HD or planned outside trial
 1 = LHRH agonist, e.g. Zoladex, with short course anti-androgen
 2 = Bicalutamide monotherapy 150mg/daily e.g. Casodex
 3 = LHRH antagonist e.g. Degarelix

12 Has the patient completed the baseline Quality of Life form?
 0 = No (please ensure this is completed before the patient is informed of allocation if given consent to participate)
 1 = Yes

To randomise, please call MRC: 020 7670 4777 or NCIC CTG: 613 533 6430

13 Allocated treatment - RADICALS-RT
 1 = Early radiotherapy
 2 = Deferred radiotherapy

14 Allocated treatment - RADICALS-HD
 1 = RT alone
 2 = RT + 6m HT
 3 = RT + 2y HT
 4 = Not taking part in RADICALS-HD right now (If the patient decides to take part in RADICALS-HD at any time, please complete CRF4)

15 MRC Patient ID No.

16 NCIC CTG Patient ID No.

Signed by
(only MRC authorised person / NCIC CTG investigator)

Date
d m y

ELIGIBILITY CRITERIA

Main entry criteria

- Patient has undergone radical prostatectomy
- Written informed consent

RT Timing Randomisation

- Post-operative serum PSA <0.2 ng/ml
- Ideally more than 4 weeks and less than 22 weeks after radical prostatectomy
- One or more of:
 - pT3/4
 - Gleason 7 - 10 (biopsy or surgical sample)
 - Pre-operative PSA ≥10ng/ml
 - Positive margins

Hormone Duration Randomisation

- Patient due to receive post-operative radiotherapy (early or deferred)

Please complete this form every 4 months for 2 years, then 6 monthly until 5 years and annually thereafter.

Keep a photocopy for your records and send original to your trials unit:

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Patient's initials
F M L

Date of birth
d m y

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Hospital No. Responsible investigator Institution

Please complete this form with information for the period between the last follow-up and now.

Which Follow-up Report: _____ mths / yrs (please delete as appropriate)

1
d m y Date of follow up visit

2 . PSA value

3
d m y Date PSA value taken

4 Was there a 'disease event' since last follow-up (see box)
0 = No
1 = Yes - complete an event form

DISEASEEVENTS

- Castration resistant disease progression
- Biochemical progression
- Clinical progression
- Metastases
- Death
- Non-protocol hormone treatment
- Second primary cancer

Definitions of these can be found in section 9.2 of the protocol

5 LHRH agonists/analogues since last follow-up (if this is first follow-up visit, please give start date).
0 = None
1 = Started
2 = Continuing
3 = Stopped

6
d m y Date (if started or stopped)

7 Anti-androgens since last follow-up (excluding for disease flare)(if this is first follow-up visit, please give start date).
0 = None
1 = Started
2 = Continuing
3 = Stopped

8
d m y Date (if started or stopped)

9 Orchiectomy since last follow-up
0 = No
1 = Yes

10
d m y Date of orchiectomy

Please give the RTOG toxicity grade for each of the following symptoms over the past 4 weeks:

- 11 Diarrhoea
- 12 Proctitis
- 13 Cystitis
- 14 Haematuria
- 15 Urethral stricture

RTOG TOXICITY GRADING SYSTEM

Grade	Symptoms
0	No Symptoms
1	Minor symptoms requiring no treatment
2	Symptoms responding to simple outpatient management, lifestyle (performance status)
3	Distressing symptoms altering patient's lifestyle (performance status). Hospitalisation for diagnosis or minor surgical intervention (such as urethral dilation) may be required
4	Major surgical intervention (such as laparotomy colostomy, cystectomy) or prolonged hospitalisation required
5	Fatal complications

Please fax to 020 7670 4818 within 1 working day of identification of event for the attention of: Claire Murphy, Trial Manager

1 Patient's initials F M L
 2 Date of birth d m y
 3 MRC Patient ID No.
 NCIC CTG Patient ID No.
 4 Hospital No. 5 Responsible clinician
 6 Country 7 Institution

8 Type of report 1 = First
 2 = Follow-up, number
 9 Trial arm 1 = RT + no HT
 2 = RT + 6 mo HT
 3 = RT + 2yr HT
 4 = Salvage RT policy
 10 Sex 1 = Male
 2 = Female
 11 Height N/A cm
 12 Weight N/A kg
 13 Body Surface Area N/A m²

14 Was the event serious? 0 = No
 1 = Yes
 15 Why was the event serious?
 1 = Resulted in death
 2 = Life-threatening
 3 = Required inpatient hospitalisation or prolongation of existing hospitalisation
 4 = Persistent or significant disability/incapacity
 5 = Congenital anomaly/birth defect
 6 = Other important medical condition, specify.....
 16 Where did SAE take place?
 1 = Hospital
 2 = Out-patient clinic
 3 = Home
 4 = Nursing home
 5 = Other, specify.....

Details of SAE				
17 Main diagnosis/symptom (Enter the MAIN EVENT in the first row, followed by any associated symptoms.)	18 Grade (<CTCAE v3.0> or <DAIDS> or <see protocol>)	19 Date of onset dd / mm / yyyy	20 SAE Status 1 = Resolved 2 = Resolved with sequelae 3 = Ongoing 4 = Worsened 5 = Fatal	21 Date resolved dd / mm / yyyy
Associated symptoms:				

Trial medications							
23 Trial drug	24 Date of first administration dd / mm / yyyy	25 Actual dose given at most recent administration	26 Date of most recent administration dd / mm / yyyy	27 Route 1 = Oral 2 = Intravenous 3 = Subcutaneous 4 = Other	28 Causal relationship to SAE 1 = Definitely 2 = Probably 3 = Possibly 4 = Unlikely 5 = Not related 6 = Administration	29 Expectedness* 1 = Expected 2 = Unexpected	30 Action taken due to SAE 0 = None 1 = Dose reduction 2 = Treatment delayed 3 = Treatment reduced & delayed 4 = Treatment stopped

* Was the event one of the recognised undesirable effects of the trial medication?

Radiotherapy and other treatments (Include concomitant medication, radiotherapy, surgery and palliative care; exclude any therapy given for management of SAE. Continue on a separate sheet if necessary).							
31 Treatment Give generic name	32 Total Daily Dose	33 Route 1 = Oral 2 = Intravenous 3 = Subcutaneous 4 = Other	34 Start Date dd / mm / yyyy	35 Ongoing 0 = No 1 = Yes	36 End Date dd / mm / yyyy	37 Causal relationship 1 = Definitely 2 = Probably 3 = Possibly 4 = Unlikely 5 = Not related 6 = Administration	38 Action taken 0 = None 1 = Dose reduction 2 = Treatment delayed 3 = Treatment reduced and delayed 4 = Treatment stopped

Signed by Clinician _____ Date of completion
 (only MRC authorised person / NCIC CTG investigator) d m y

RADICALS Quality of Life Form

For patients in RADICALS-RT (Radiotherapy Timing Comparison) only

Guidance

1. We are interested in some things about you and your health. Please answer all of the questions **yourself**.
2. **Circle the number** or **tick the box** that best applies to you.
3. There are no "right" or "wrong" answers.
4. The information that you provide will remain **strictly confidential**.
5. Once completed, return to the nurse or study doctor
6. The nurse or study doctor must post to:
UK: RADICALS Data Manager, MRC Clinical Trials Unit, Aviation House, 125 Kingsway, London, WC2B 6NH, UK
Canada: Clinical Trials Assistant, NCIC CTG, Queen's University, 10 Stuart St., Kingston, Ontario K7L 3N6, Canada

"Clinical trials, such as RADICALS, are essential to determine the best treatment for a disease. In a trial, **it is vital that patients are able to report the impact of treatment on their quality of life**. For this reason, you are being asked to complete the questions below. **Your feedback is a very important part of the trial**. If you have any difficulties with this, please discuss them with your study doctor or nurse specialist."

- **Jim Stansfeld**, PCaSO and patient member of the RADICALS team

For patients in RADICALS-RT (Radiotherapy Timing Comparison) only

Patient's initials

Date of birth
d m y

MRC Patient ID No.

NCIC CTG Patient ID No.

UK Patient's postcode:

UK Patient NHS Number:.....

Quality of Life Timepoint (please circle): **Baseline** | 1yr | 5 yr | 10yr

Question Group 1: SF12

	Excellent	Very good	Good	Fair	Poor
¹ In general, would you say your health is:	1	2	3	4	5

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
² <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
³ Climbing <u>several</u> flights of stairs	1	2	3

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
⁴ <u>Accomplished less</u> than you would like	1	2	3	4	5
⁵ Were limited in the <u>kind</u> of work or other activities	1	2	3	4	5

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
⁶ <u>Accomplished less than you would like</u>	1	2	3	4	5
⁷ Did work or activities <u>less carefully than usual</u>	1	2	3	4	5
	Not at all	A little bit	Moderately	Quite a bit	Extremely
⁸ During the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?	1	2	3	4	5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
⁹ Have you felt calm and peaceful?	1	2	3	4	5
¹⁰ Did you have a lot of energy?	1	2	3	4	5
¹¹ Have you felt downhearted and depressed?	1	2	3	4	5
¹² During the <u>past 4 weeks</u> , how much of your time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?	1	2	3	4	5

Question Group 3: ICSMALESF

	Never	Occasionally	Sometimes	Most of the time	All of the time
¹ Is there a delay before you can start to urinate?	1	2	3	4	5
² Do you have to strain to continue urinating?	1	2	3	4	5
	Normal	Occasionally reduced	Sometimes reduced	Reduced most of the time	Reduced all of the time
³ Would you say that the strength of your urinary stream is...	1	2	3	4	5
	Never	Occasionally	Sometimes	Most of the time	All of the time
⁴ Do you stop and start more than once when you urinate?	1	2	3	4	5
⁵ How often do you feel that your bladder has not emptied properly after you have urinated?	1	2	3	4	5
⁶ Do you have to rush to the toilet to urinate?	1	2	3	4	5
⁷ Does urine leak before you can get to the toilet?	1	2	3	4	5
⁸ Does urine leak when you cough or sneeze?	1	2	3	4	5
⁹ Do you ever leak for no obvious reason and without feeling that you want to go?	1	2	3	4	5
¹⁰ Do you leak urine when you are asleep?	1	2	3	4	5
¹¹ How often have you had a slight wetting of your pants a few minutes after you had finished urinating and had dressed yourself?	1	2	3	4	5

	Hourly	Every 2 hours	Every 3 hours	Every 4 hours or more	
¹² How often do you pass urine during the day?	1	2	3	4	
	None	One	Two	Three	Four or more
¹³ During the night, how many times do you have to get up to urinate on average?	1	2	3	4	5
	Not at all	A little	Somewhat	A lot	
¹⁴ Overall, how much do your urinary symptoms interfere with your life?	1	2	3	4	
	No	Yes			
¹⁵ Do you take medication for your bladder?	1	2			
Please specify the type of medication.....					
	No	Yes			
¹⁶ Have you had previous surgery for incontinence?	1	2			

Question Group 4: Vaizey

	Never	Rarely	Sometimes	Weekly	Daily
¹ Incontinence for solid stool	1	2	3	4	5
² Incontinence for liquid stool	1	2	3	4	5
³ Incontinence for gas	1	2	3	4	5
⁴ Alteration to lifestyle	1	2	3	4	5
	No	Yes			
⁵ Need to wear a pad or plug	1	2			
⁶ Taking constipation medicines	1	2			
⁷ Lack of ability to defer defecation for 15 minutes	1	2			

Key

Never No episodes in the past 4 weeks

Rarely 1 episode in the past 4 weeks

Sometimes More than 1 episode in the past 4 weeks but less than 1 per week

Weekly 1 or more episodes a week but less than 1 per day

Daily 1 or more episodes per day

Question Group 5: IIEF5

	Very low	Low	Moderate	High	Very high	
¹ Over the past 4 weeks how do you rate your confidence that you can get and keep your erection?	1	2	3	4	5	
	No sexual activity	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
² Over the past 4 weeks when you had erections with sexual stimulation, how often were your erections hard enough for penetration?	1	2	3	4	5	6
	Did not attempt intercourse	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
³ Over the past 4 weeks during sexual intercourse, <i>how often</i> were you able to maintain your erection after you had penetrated (entered) your partner?	1	2	3	4	5	6
	Did not attempt intercourse	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
⁴ Over the past 4 weeks during sexual intercourse, <i>how difficult</i> was it to maintain your erection to completion of intercourse?	1	2	3	4	5	6
	No sexual activity	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
⁵ Over the past 4 weeks when you attempted sexual intercourse, <i>how often</i> was it satisfactory for you?	1	2	3	4	5	6
⁶ Do you use any sexual support? (please circle)	No	Yes				
⁷ If yes, please specify the type of support (please circle)		Medication	Yes	No		
		Pump	Yes	No		
		Implant	Yes	No		
		Other	Yes	No		
		If other, please specify.....				