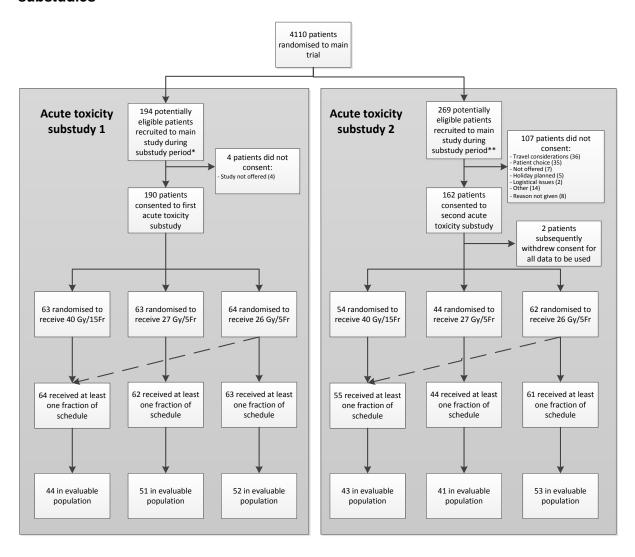
SUPPLEMENTARY FILES

Appendix 1: Flow diagram of participation in the first and second acute toxicity substudies



Appendix 2: Baseline characteristics of patients in first and second acute toxicity substudies

	Acute toxicity substudy 1			Acute	Acute toxicity substudy 2			
Baseline characteristics	40 Gy/15F	27 Gy/5F	26 Gy/5F	40Gy/15fr	27Gy/5fr	26Gy/5fr		
Baseline Characteristics	N=63	N=63	N=64	N=54	N=44	N=62		
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)		
Age								
Median (IQR)	63 (57 - 69)	65 (54 - 68)	63 (55 - 68)	60 (54-66)	61 (56-70)	61 (54-64)		
Range	46-87	41-82	44-86	47-81	49-84	42-78		
Age category								
<50	5 (8)	11 (17)	10 (16)	3 (5)	2 (5)	6 (10)		
≥50	58 (92)	52 (83)	54 (84)	52 (95)	42 (95)	57 (90)		
Tumour grade								
1	15 (24)	16 (25)	17 (27)	14 (25)	10 (23)	16 (25)		
2	28 (44)	31 (49)	33 (52)	27 (49) 23 (52)		34 (54)		
3	20 (32)	16 (25)	14 (22)	14 (25)	11 (25)	13 (21)		
Risk group								
Low (≥50 & grade 1 or 2)	40 (63)	39 (62)	43 (67)	38 (69) 31 (70) 45		45 (71)		
High (<50 and/or grade 3)	23 (37)	24 (38)	21 (33)	17 (31)	13 (30)	18 (29)		
Boost planned								
No	54 (86)	52 (83)	59 (92)	55 (100)	44 (100)	63 (100)		
Yes	9 (14)	11 (17)	5 (8)	0	0	0		

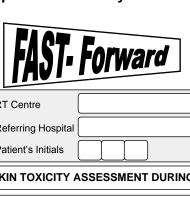
Appendix 3: Modified RTOG and CTCAEv4.03 definitions used in first and second acute skin toxicity sub-studies

Acute toxicity substudy 1			
*Modified RTOG	Description		
Grade 1	Faint/dull erythema		
Grade 2	Tender/bright erythema +/- dry desquamation		
Grade 3	Patchy moist desquamation, moderate oedema		
Grade 4	Confluent moist desquamation, pitting oedema		

Acute toxicity substudy 2			
CTCAEv4.03	Description		
Grade 1	Faint erythema or dry desquamation		
Grade 2	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin fold; moderate oedema		
Grade 3	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion		
Grade 4	Life threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated		

^{*}The inclusion of oedema in the modified RTOG system proved unhelpful in this particular context, since the primary concern was to score moist desquamation; hence the second substudy was undertaken using CTCAE criteria

Appendix 4: Toxicity assessment form



Skin Toxicity During Radiotherapy:

IAVI-IVIII					Contr	oi group
RT Centre		Trial nu	umber FF			
Referring Hospital						
Patient's Initials	Date	of Birth	Day	Month		ear
SKIN TOXICITY ASSESSMENT DURING R.	ADIOTHE	RAPY: C				
Date RT started	\uparrow	\bigcap				
Day Month	Year					
Assessments are to be carried out by a healthcare professional <u>weekly</u> . Please specify <u>date</u> of each assessment and <u>tick</u> the appropriate box indicating grade according to the CTCAE scoring criteria. If grade 1 or 2 please <u>also</u> tick the relevant symptom(s)						
<u></u>	Before RT begins	During 1st week	During 2nd week	During 3rd week	Only comp duration>3	
Date of assessment	begins	week	week	week	duration>3	weeks
CTCAE grade						
0 (no toxicity)						
1 Please tick all relevant symptoms	***************************************		***************************************	000000000000000000000000000000000000000	***************************************	
faint erythema	,	,	,	,		
dry desquamation Please tick all relevant symptoms						
moderate to brisk erythema	~~~~		***************************************			
patchy moist desquamation confined to skin folds/creases						
moderate oedema						
3						
4						
5						
* If any assessment was not done please contact the patient and complete the Missed Assessment Form ** If radiotherapy is delayed and extends beyond 3 weeks then additional weekly toxicity assessments will be required during radiotherapy – please complete as required						
			•	•	pace provid	ded
CTCAE v4.03 Dermatitis radiation	oc add arry	Oli IOI TOIOV	ant commo	THO III THE C	pace provid	
1 Faint erythema or dry desquamation 2 Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema 3 Moist desquamation in areas other						
than skin folds and creases; bleeding induced by minor trauma or abrasion						
Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated						
5 Death						
Signature						
Print Name		Date form completed		Month		Year
Received	offi	CA		Checked	1/1/	
TRAQS Initials	Jane	Initia		, 01	ll y	nitials
FAST-Forwa	ra CRFs vers	ion 3.0 16/0	15/2013			

Appendix 5: Missed assessment form



Missed Assessment Form

RT Centre	Trial number FF
Referring Hospital	
Patient's Initials	Date of Birth Day Month Year
TO BE COMPLETED II	F A PATIENT DOES NOT ATTEND FOR A TOXICITY ASSESSMENT
Was the patient called if the	hey failed to turn up for a toxicity assessment? Yes* No**
* If yes, please complete	e the rest of this form
** If no, please specify re	eason
Date of telephone assess	Day Month Year
i ne patient snould be asi	ked the following questions:
Please state reason for nan assessment	ot attending for
Has there been any chan-	ge in skin colour since last week?
Yes, less pink/red	Yes, more pink/red No, same colour
ls there been any eviden	ce of skin weeping or oozing?
is there seen any eviden	Yes* No
* If yes, please specify the	Skin creases/folds Other
Signature	
Print Name	Date form completed Day Month Year
Received	Entered Checked
For	The Soffice Bondy Initials Initials