



Clinical trial results:

Etude randomisée multicentrique comparant une radiothérapie adjuvante immédiate associée à une hormonothérapie courte par analogue LH-RH (Décapeptyl LP®) vs une radiothérapie différée à la rechute biochimique associée à une hormonothérapie courte par analogue LH-RH (Décapatyl LP®) chez les patients opérés d'un cancer de la prostate pT3 R1 pN0 ou pNX, de risque intermédiaire

Summary

EudraCT number	2007-002495-34
Trial protocol	FR
Global end of trial date	24 July 2022

Results information

Result version number	v1 (current)
This version publication date	01 February 2025
First version publication date	01 February 2025

Trial information

Trial identification

Sponsor protocol code	GETUG 17/0702
-----------------------	---------------

Additional study identifiers

ISRCTN number	ISRCTN00667069
ClinicalTrials.gov id (NCT number)	NCT00667069
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UNICANCER
Sponsor organisation address	101 rue de Tolbiac, Paris, France, 75013
Public contact	Nourredine AIT RAHMOUNE, UNICANCER, 33 0171936704, n.ait-rahmoune@unicancer.fr
Scientific contact	Nourredine AIT RAHMOUNE, UNICANCER, 33 0171936704, n.ait-rahmoune@unicancer.fr

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 December 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 August 2019
Global end of trial reached?	Yes
Global end of trial date	24 July 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of aRT combined with hormonal therapy immediately after RP to sRT combined with hormonal therapy at biochemical relapse.

Protection of trial subjects:

This study was conducted in accordance with the Declaration of Helsinki (1964) and subsequent amendments, ICH Good Clinical Practice (GCP) Guidelines (CPMP/ICH/135/95), the European Directive (2001/20/CE) and the applicable local regulatory requirements and laws.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 April 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 424
Worldwide total number of subjects	424
EEA total number of subjects	424

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	240
From 65 to 84 years	184

85 years and over	0
-------------------	---

Subject disposition

Recruitment

Recruitment details:

The trial planned to enrol 718 patients, 359 in each study arm. However, an independent data monitoring committee held on the 20-May-2016 recommended that accrual be stopped. Finally, the trial enrolled 424 patients: 212 in the aRT Arm and 212 in the sRT Arm. The first patient was randomised on 07/04/2008.

Pre-assignment

Screening details:

Randomisation was performed at least 3 months and at the latest 6 months after radical prostatectomy. At randomisation, it was necessary to verify that the PSA level post-intervention was ≤ 0.1 ng/mL at two dosages, 2 months apart, for patient eligibility.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	aRT Arm

Arm description:

In the aRT Arm, hormonal therapy was planned to start within the 2 months before RT. The initiation of RT was planned between 3 and 6 months after RP.

Arm type	Experimental
Investigational medicinal product name	Triptorelin (Decapeptyl®)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One injection every 3 months for 6 months, i.e., 2 injections

Arm title	sRT Arm
------------------	---------

Arm description:

In the sRT Arm, RT combined with hormonal therapy (identical to the aRT Arm) was initiated once biochemical relapse had occurred.

Arm type	Active comparator
Investigational medicinal product name	Triptorelin (Decapeptyl®)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One injection every 3 months for 6 months, i.e., 2 injections

Number of subjects in period 1	aRT Arm	sRT Arm
Started	212	212
Completed	198	107
Not completed	14	105
Refused Radiotherapy	1	-
Patient decision	-	1
Lost to follow up	-	2
Toxicity	1	2
Death	1	-
Did not receive hormonal therapy	3	1
Consent withdrawn	4	2
Missing data	4	97

Baseline characteristics

Reporting groups

Reporting group title	aRT Arm
Reporting group description:	
In the aRT Arm, hormonal therapy was planned to start within the 2 months before RT. The initiation of RT was planned between 3 and 6 months after RP.	
Reporting group title	sRT Arm
Reporting group description:	
In the sRT Arm, RT combined with hormonal therapy (identical to the aRT Arm) was initiated once biochemical relapse had occurred.	

Reporting group values	aRT Arm	sRT Arm	Total
Number of subjects	212	212	424
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	116	124	240
From 65-84 years	96	88	184
85 years and over	0	0	0
Age continuous			
Age at randomisation (years)			
Units: years			
median	63.0	63.0	
full range (min-max)	44 to 76	36 to 77	-
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	212	212	424
PT3AOUB			
Units: Subjects			
pT3A ou pT4	168	168	336
pT3B	44	44	88
GRADE			
Units: Subjects			
Grade 4 non prédominant	138	137	275
Grade 4 prédominant	74	75	149
ECOG performance status			
Units: Subjects			
ECOG 0	195	194	389
ECOG 1	12	13	25
Missing data	5	5	10

Gleason score			
Units: Subjects			
Gleason score 3	0	1	1
Gleason score 5	1	0	1
Gleason score 6	20	21	41
Gleason score 7	173	167	340
Gleason score 8	12	16	28
Gleason score 9	5	7	12
Missing data	1	0	1
pT-staging			
Units: Subjects			
pT3a	163	163	326
pT3b	45	43	88
pT4 (bladder neck)	3	5	8
Missing data	1	1	2
pN-staging			
Units: Subjects			
pN0	153	151	304
pNx	58	61	119
Missing data	1	0	1
Positive surgical margins			
Units: Subjects			
No	0	2	2
Yes	211	210	421
Missing data	1	0	1
Seminal vesicles invasion			
Units: Subjects			
Non-invaded	167	165	332
Invaded	44	46	90
Missing data	1	1	2
Age at prostatectomy			
Units: Years			
median	63.4	63.7	
full range (min-max)	0 to 77	-1 to 76	-
Time interval since prostatectomy			
Units: Months			
median	3.4	3.4	
full range (min-max)	1 to 7	1 to 8	-

End points

End points reporting groups

Reporting group title	aRT Arm
Reporting group description:	
In the aRT Arm, hormonal therapy was planned to start within the 2 months before RT. The initiation of RT was planned between 3 and 6 months after RP.	
Reporting group title	sRT Arm
Reporting group description:	
In the sRT Arm, RT combined with hormonal therapy (identical to the aRT Arm) was initiated once biochemical relapse had occurred.	

Primary: EFS rate at 5 years

End point title	EFS rate at 5 years
End point description:	
End point type	Primary
End point timeframe:	
5 years after randomisation	

End point values	aRT Arm	sRT Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	212	212		
Units: percent				
number (confidence interval 95%)	92 (86 to 95)	90 (85 to 94)		

Statistical analyses

Statistical analysis title	EFS rate analysis
Comparison groups	sRT Arm v aRT Arm
Number of subjects included in analysis	424
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 42
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.36

Secondary: OS rate at 5 years

End point title	OS rate at 5 years
-----------------	--------------------

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

5 years after randomisation

End point values	aRT Arm	sRT Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	212	212		
Units: percent				
number (confidence interval 95%)	96 (92 to 98)	99 (96 to 100)		

Statistical analyses

Statistical analysis title	OS rate analysis
----------------------------	------------------

Comparison groups	aRT Arm v sRT Arm
-------------------	-------------------

Number of subjects included in analysis	424
---	-----

Analysis specification	Pre-specified
------------------------	---------------

Analysis type	superiority
---------------	-------------

P-value	= 0.25
---------	--------

Method	Logrank
--------	---------

Parameter estimate	Hazard ratio (HR)
--------------------	-------------------

Point estimate	1.6
----------------	-----

Confidence interval

level	95 %
-------	------

sides	2-sided
-------	---------

lower limit	0.71
-------------	------

upper limit	3.6
-------------	-----

Secondary: The mean global health status at baseline

End point title	The mean global health status at baseline
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

from baseline until December 2017

End point values	aRT Arm	sRT Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	212	212		
Units: Number				
log mean (standard deviation)	76.2 (± 19)	76.4 (± 19.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The analysis of the incidence of AEs was divided into acute toxicities, those occurring during radiotherapy and within 3 months of completing radiotherapy, and late toxicities, those occurring after this period and during at most 5 years of follow up.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	aRT Arm
-----------------------	---------

Reporting group description: -

Reporting group title	sRT Arm
-----------------------	---------

Reporting group description: -

Serious adverse events	aRT Arm	sRT Arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	35 / 212 (16.51%)	37 / 212 (17.45%)	
number of deaths (all causes)	14	10	
number of deaths resulting from adverse events	1	2	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	2 / 212 (0.94%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma of kidney			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of the cardia			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma pancreas			

subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anal squamous cell carcinoma			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carcinoma kidney			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoma larynx			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphatic leukemia			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphoid leukaemia			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	2 / 212 (0.94%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			

subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma, unclassifiable, NOS			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epidermoid carcinoma			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infiltrating ductal breast cancer			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplasia			

subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelofibrosis			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myeloma			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neoplasm of unspecified nature of digestive system			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-small cell lung cancer			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreas cancer			
subjects affected / exposed	2 / 212 (0.94%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pancreatic adenocarcinoma			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal adenocarcinoma			

subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal cancer metastatic			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Thyroid carcinoma			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urothelial carcinoma			
subjects affected / exposed	0 / 212 (0.00%)	4 / 212 (1.89%)	
occurrences causally related to treatment / all	0 / 0	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urothelial carcinoma bladder			
subjects affected / exposed	1 / 212 (0.47%)	3 / 212 (1.42%)	
occurrences causally related to treatment / all	0 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Arteritis obliterans			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial disease			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hip prosthesis insertion			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchidectomy			

subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Unknown cause of death			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Injury, poisoning and procedural complications			
Irradiation cystitis			
subjects affected / exposed	1 / 212 (0.47%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina at rest			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac insufficiency			
subjects affected / exposed	2 / 212 (0.94%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Generalized tonic-clonic seizure			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial epilepsy			

subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Congenital deafness			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Bleeding rectal			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernial eventration			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	1 / 212 (0.47%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic duct stenosis			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Renal and urinary disorders			
Acute retention of urine			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis radiation			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	1 / 212 (0.47%)	5 / 212 (2.36%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stenosis of vesicourethral anastomosis			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stenosis ureteral			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	2 / 212 (0.94%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Diabetes			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Diabetes mellitus loss of control subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes with hyperosmolarity subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Colonic abscess			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Community acquired pneumonia			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrenous cholecystitis			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	aRT Arm	sRT Arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	212 / 212 (100.00%)	212 / 212 (100.00%)	
Vascular disorders			

Hypertension subjects affected / exposed occurrences (all)	4 / 212 (1.89%) 1	3 / 212 (1.42%) 1	
Hypotension subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	
General disorders and administration site conditions			
Hot flush subjects affected / exposed occurrences (all)	83 / 212 (39.15%) 1	36 / 212 (16.98%) 1	
Asthenia subjects affected / exposed occurrences (all)	41 / 212 (19.34%) 1	19 / 212 (8.96%) 1	
Pain subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 1	0 / 212 (0.00%) 0	
Immune system disorders			
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 212 (0.47%) 1	
Reproductive system and breast disorders			
Erectile dysfunction subjects affected / exposed occurrences (all)	11 / 212 (5.19%) 1	7 / 212 (3.30%) 1	
Breast tenderness subjects affected / exposed occurrences (all)	4 / 212 (1.89%) 1	1 / 212 (0.47%) 1	
Gynecomastia subjects affected / exposed occurrences (all)	3 / 212 (1.42%) 1	2 / 212 (0.94%) 1	
Libido disorder subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 1	0 / 212 (0.00%) 0	
Ejaculation disorder subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	

Testicular pain subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 212 (0.47%) 1	
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all) Dysphonia subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0 1 / 212 (0.47%) 1	2 / 212 (0.94%) 1 0 / 212 (0.00%) 0	
Investigations Weight decreased subjects affected / exposed occurrences (all)	13 / 212 (6.13%) 1	3 / 212 (1.42%) 1	
Injury, poisoning and procedural complications Fracture subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all) Presyncope subjects affected / exposed occurrences (all) Sciatica subjects affected / exposed occurrences (all)	3 / 212 (1.42%) 1 1 / 212 (0.47%) 1 1 / 212 (0.47%) 1 1 / 212 (0.47%) 1	0 / 212 (0.00%) 0 0 / 212 (0.00%) 0 0 / 212 (0.00%) 0 0 / 212 (0.00%) 0	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Proctitis	60 / 212 (28.30%) 1	17 / 212 (8.02%) 1	

subjects affected / exposed	27 / 212 (12.74%)	6 / 212 (2.83%)
occurrences (all)	1	1
Anal inflammation		
subjects affected / exposed	22 / 212 (10.38%)	5 / 212 (2.36%)
occurrences (all)	1	1
Flatulence		
subjects affected / exposed	19 / 212 (8.96%)	8 / 212 (3.77%)
occurrences (all)	1	1
Rectal haemorrhage		
subjects affected / exposed	16 / 212 (7.55%)	5 / 212 (2.36%)
occurrences (all)	1	1
Constipation		
subjects affected / exposed	6 / 212 (2.83%)	8 / 212 (3.77%)
occurrences (all)	1	1
Haemorrhoids		
subjects affected / exposed	11 / 212 (5.19%)	2 / 212 (0.94%)
occurrences (all)	1	1
Abdominal pain		
subjects affected / exposed	5 / 212 (2.36%)	1 / 212 (0.47%)
occurrences (all)	1	1
Anorectal discomfort		
subjects affected / exposed	3 / 212 (1.42%)	1 / 212 (0.47%)
occurrences (all)	1	1
Abdominal pain upper		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Aerophagia		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Anal fissure		
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)
occurrences (all)	0	1
Anal pruritus		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Ascites		

subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Bowel motility disorder		
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)
occurrences (all)	0	1
Dyschezia		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Dysphagia		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Frequent bowel movements		
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)
occurrences (all)	0	1
Gastroenteritis		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Gastrointestinal disorder		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Gastrointestinal motility disorder		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Gastrointestinal toxicity		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Gastrointestinal tract irritation		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Inguinal hernia		
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)
occurrences (all)	1	0
Intestinal obstruction		
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)
occurrences (all)	0	1
Mucous stools		

subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences (all)	1	0	
Proctalgia			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences (all)	1	0	
Rectal tenesmus			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences (all)	0	1	
Mucosal inflammation			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	18 / 212 (8.49%)	10 / 212 (4.72%)	
occurrences (all)	1	1	
Rash			
subjects affected / exposed	3 / 212 (1.42%)	2 / 212 (0.94%)	
occurrences (all)	1	1	
Radiation skin injury			
subjects affected / exposed	1 / 212 (0.47%)	2 / 212 (0.94%)	
occurrences (all)	1	1	
Erythema			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences (all)	1	0	
Pruritus			
subjects affected / exposed	1 / 212 (0.47%)	0 / 212 (0.00%)	
occurrences (all)	1	0	
Skin burning sensation			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences (all)	0	1	
Skin hyperpigmentation			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences (all)	0	1	
Skin irritation			
subjects affected / exposed	0 / 212 (0.00%)	1 / 212 (0.47%)	
occurrences (all)	0	1	

Skin ulcer subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	
Renal and urinary disorders			
Pollakiuria subjects affected / exposed occurrences (all)	107 / 212 (50.47%) 1	38 / 212 (17.92%) 1	
Urinary incontinence subjects affected / exposed occurrences (all)	48 / 212 (22.64%) 1	10 / 212 (4.72%) 1	
Dysuria subjects affected / exposed occurrences (all)	32 / 212 (15.09%) 1	13 / 212 (6.13%) 1	
Micturition urgency subjects affected / exposed occurrences (all)	8 / 212 (3.77%) 1	5 / 212 (2.36%) 1	
Nocturia subjects affected / exposed occurrences (all)	7 / 212 (3.30%) 1	6 / 212 (2.83%) 1	
Cystitis radiation subjects affected / exposed occurrences (all)	4 / 212 (1.89%) 1	0 / 212 (0.00%) 0	
Micturition disorder subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 1	1 / 212 (0.47%) 1	
Haematuria subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	1 / 212 (0.47%) 1	
Urinary retention subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 1	0 / 212 (0.00%) 0	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	3 / 212 (1.42%) 1	1 / 212 (0.47%) 1	
Muscular weakness			

subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 1	1 / 212 (0.47%) 1	
Back pain subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	
Bone pain subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	
Groin pain subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	
Neck pain subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 0	0 / 212 (0.00%) 0	
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	2 / 212 (0.94%) 1	2 / 212 (0.94%) 1	
Herpes zoster subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 212 (0.47%) 1	
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	
Streptococcal infection subjects affected / exposed occurrences (all)	0 / 212 (0.00%) 0	1 / 212 (0.47%) 1	
Metabolism and nutrition disorders Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	1 / 212 (0.47%) 1	0 / 212 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 November 2007	- Clarification of the primary objective. - Correction of the email address for randomisation. - Updating of the investigator list.
26 March 2008	- Clarification of the definition of biochemical relapse in the salvage radiotherapy (sRT) Arm. - Updating of the investigator list.
30 July 2008	- Updating of the investigator list.
25 February 2009	- Modification of the project leader - Updating of the investigator list.
24 June 2009	- Updating of the investigator list.
30 September 2009	- Updating of the investigator list
16 December 2009	- Lowering of the maximum PSA levels to initiate treatment in the sRT Arm from >2 ng/mL to >1 ng/mL. - Updating of the investigator list.
27 January 2010	- Updating of the investigator list.
31 March 2010	- Updating of the investigator list.
28 July 2010	- Updating of the investigator list.
30 March 2011	- Updating of the investigator list.
21 December 2011	- Changing of the promoter from Fédération Nationale des Centres de Lutte Contre le Cancer (FNCLCC) to Unicancer. Consequently, the study management team and all the contact details were also modified.
29 February 2012	- Updating of the investigator list.
12 December 2012	- Updating of the investigator list. - Prolongation of the inclusion period by 24 months, thus until December 2014.
28 August 2013	- Updating of the investigator list.
24 February 2014	- Updating of the investigator list. - Correction of errors in the protocol, corresponding to Amendment N°7.
29 October 2014	- Updating of the investigator list. - Correction of an error in the protocol.

25 February 2015	- Updating of the investigator list.
27 May 2015	- Updating of the investigator list.
29 July 2015	- Updating of the investigator list.
28 October 2015	- Updating of the investigator list.
27 January 2016	- Updating of the investigator list. - Prolongation of the inclusion period by 12 months.
28 September 2016	- Updating of the investigator list
27 July 2017	- Updating of the investigator list. - Collection of QLQ for all patients
27 June 2018	- Updating of the investigator list.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
20 May 2016	The GETUG-AFU 17 trial planned to enrol 718 patients, 359 in each study arm. However, an IDMC held on the 20-May-2016 recommended that accrual be stopped. The accrual was stopped, on the 23-Jun-2016, 424 patients had been randomly allocated: 212 to the aRT Arm and 212 to the sRT Arm.	-

Notes:

Limitations and caveats

None reported