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Phase II study of extreme hypofractionated radiotherapy for localized prostate cancer

Submission date 11/07/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/07/2018	**Overall study status** Completed	
Last Edited 06/08/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Radiotherapy is a treatment where radiation is used to kill cancer cells and can be used to treat prostate cancer. The effectiveness of radiotherapy for the treatment of prostate cancer improves when high doses are delivered to the prostate, especially in aggressive, localised prostate cancer. The standard method of radiotherapy is to deliver small daily doses over the course of 8 weeks; however, as the dose increases over this time, so do the side effects. Recent evidence shows that, instead of small doses over a longer time period, higher daily doses over a few weeks, mean that higher doses of radiotherapy can be given without increasing the side effects of the treatment, along with improving rates of curing the cancer. This has been shown in patients with low-risk and some patients with intermediate-risk prostate cancer.
We aim to look at whether similar results can be achieved for patients with intermediate-risk and high-risk prostate cancer through 8 days of high dose radiotherapy.

Who can participate?
Localised prostate cancer patients

What does the study involve?
All participants receive high dose radiotherapy on 8 days across 3 weeks, along with traditional androgen deprivation therapy. Additionally, patients will be regularly tested for toxicity, PSA levels and metastasis for 10 years following the study.

What are the possible benefits and risks of participating?
The benefits to participants of taking part include potential curing of their cancer with reduced side effects, along with an improved quality of life. Additionally, the treatment scheme is short, which is more convenient for patients. A possible risk of taking part is unexpected toxicity/side effects.

Where is the study run from?
Salamanca University Hospital, Spain

When is the study starting and how long is it expected to run for?
January 2012 to December 2022

Who is funding the study?
Castille-Leon Autonomous Community public health system (Spain)

Who is the main contact?
Dr Victor Macias-Hernandez (radiation oncologist/clinical oncologist)
victormaciash@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr VICTOR MACIAS-HERNANDEZ

ORCID ID
https://orcid.org/0000-0003-2904-5715

Contact details
Paseo de San Vicente
Salamanca
Spain
37007
+34687481166
victormaciash@gmail.com

Additional identifiers

Protocol serial number
GRS 903/A/14

Study information

Scientific Title
Phase II single-centre trial of Extreme Hypofractionated RAdiotherapy for low, intermediate and high-risk localised Prostate cancer

Acronym
EHRAP

Study objectives
Late toxicity, quality of life and biochemical-free survival outcomes after extreme hypofractionated radiotherapy for localized prostate cancer are not inferior to normofractionated or moderate hypofractionated radiotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)

The Spanish Agency of Medicines and Medical Devices (AEMPS) , 29/01/2013, PI 120413

Study design
Interventional prospective single-centre non-randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low, intermediate and highrisk prostate cancer

Interventions
Participants with low, intermediate and high risk prostate cancer received extreme hypofractionated radiotherapy using helical tomotherapy, with online guided MVCT and an endorectal balloon. This radiotherapy delivered 8 fractions of 5.65 Gy radiation over 3 weeks. Additionally, participants received androgen deprivation therapy as usually prescribed in normal standard - for those with intermediate-risk prostate cancer, this consisted of one 6 month LHRH analogue and 1 month bicalutamide; for those with high-risk prostate cancer, this consisted of 2-3 years of 6 month LHRH analogue and 1 month bicalutamide.
Patients will be interviewed at least 2, 6, 12, 18, 24, 30, 36, 48 and 60 months after radiotherapy and every year afterwards up to 10 years, and will be asked about symptoms, along with undergoing urine and blood tests and quality of life questionnaires. At each visit, the following will be tested:
1. Urinary and intestinal toxicity, if any, according to CTCAE scale
2. Health-related quality of life
3. PSA levels (from blood tests performed a few weeks before each visit). If a PSA relapse is found, a rectal examination will be performed to detect a local clinical relapse.
4. Metastases (examined through CT scans and bone scans)

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following are measured at the baseline and 2, 6, 12, 18, 24, 30, 36, 48 and 60 months after radiotherapy and every year afterwards:
1. Urinal and intestinal toxicities measured using CTCAE (Common Toxicity Criteria Adverse Effects) scale
2. Health-related quality of life measured using EPIC-26 (Expanded Prostate Cancer Index Composite short form)

Key secondary outcome(s))
1. PSA relapse free survival (nadir+2 ng/ml) is measured using total PSA levels (determined through blood test performed a few weeks before visit) measured at the baseline and 2, 6, 12, 18, 24, 30, 36, 48 and 60 months after radiotherapy and every year afterwards
2. Metastases-free survival is measured using a CT scan and bone scan, evaluated at the baseline and every 6 months only after a biochemical relapse is diagnosed (PSA > 2 ng + nadir, ASTRO definition)

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. cT1-T3 N0 M0 prostate cancer
2. International Prostate Symptoms Score < 21
3. No acute urinary retention or urethral surgery in the last 6 months
4. Aged 18 years or older
5. Signed specific informant consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Hip prosthesis
2. Contraindication for radical radiotherapy such as active inflamatory bowel disease, previous pelvic radiotherapy
3. Intense low urinary tract symptoms, IPSS > 20
4. Inability to understand and appreciate the nature and consequences of health decisions

Date of first enrolment
01/06/2013

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Spain

Study participating centre
Complejo Asistencial Universitario de Salamanca (Salamanca University Hospital)
Paseo de San Vicente, 137

Salamanca
Spain
37007

Sponsor information

Organisation
Hospital Universitario de Salamanca (Salamanca University Hospital)

ROR
https://ror.org/0131vfw26

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Funder Name
Spanish Autonomous Comunity grant code GRS 903/A/14, from SACYL (Castille and Leon Public Health Service)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	early toxicity results	26/11/2014		Yes	No
Results article	results	01/11/2018		Yes	No
Results article		15/10/2019	06/08/2024	Yes	No