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Effect of Decapeptyl® on prostate Volume pre-RadioTherapy

Submission date	Recruitment status	[X] Prospectively registered
01/12/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/10/2020	Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-decapeptyl-shrink-your-prostate-gland-before-radiotherapy-edvart

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-007028-25

Protocol serial number
ON/2008/2781

Study information

Scientific Title
A randomised controlled trial to determine the effect of Decapeptyl® on reduction of prostate volume pre-radiotherapy compared with standard therapy (Zoladex®)

Acronym
EDVART

Study objectives
The purpose of the study is to determine the cytoreductive efficacy of Decapeptyl® when used before radical radiotherapy (external beam radiotherapy or brachytherapy) to the prostate. Decapeptyl® will be compared in effect to Zoladex®, in order to show whether it gives as good an effect in reducing prostate size before radiotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Oxfordshire Research Ethics Committee (REC) C, 16/09/2010, ref: 10/H0606/43

Study design
Single-centre single-blind randomised active-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer patients who are due to undergo radical radiotherapy to the prostate

Interventions
Triptorelin (Decapeptyl®) 3 mg or goserelin (Zoladex®) 3.6 mg will be given for three months before radical radiotherapy. All patients will receive a 28 day course of Bicalutamide 50 mg once daily to prevent tumour flare with the first injection of their LHRHa therapy.

Each patients involvement in the study will last for 14 weeks. The study will run for 2 years and we are hoping to start in January, estimated last patient last visit is 31/01/2012.

Due to drug formulations a fully blinded study is not possible; however the doctor performing the rectal ultrasound measurements will be blinded to study treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Triptorelin (Decapeptyl®), goserelin (Zoladex®)

Primary outcome(s)
Reduction in size of prostate as measured by trans rectal ultrasound

Key secondary outcome(s))
1. Proportion of patients who reach serum testosterone castrate levels after the administration of Zoladex® and Decapeptyl®
2. Quality of life using questionnaires EQ5D, QLQ-C30 and QLQ-PR25

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Patients with histologically proven prostate cancer
2. Patients who are eligible for and have chosen radical radiotherapy (external beam or brachytherapy) as their treatment
3. The patient has given written (personally signed and dated) informed consent before starting any study-related procedure
4. The patient is male and is 18 years of age or older
5. The patient is able and willing to comply with the requirements of the protocol
6. Eastern Cooperative Oncology Group (ECOG) score 0 - 2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Total final enrolment
71

Key exclusion criteria
1. Men with stage T4 prostate cancer
2. The patient has any contraindication to treatment with anti-androgens or luteinising hormone-releasing hormone agonist (LHRHa) therapy
3. The patient has received treatment with any LHRHa or anti-androgen therapy within 1 year prior to study entry
4. The patient has been treated with oestrogens or steroid androgens within the 12 months prior to study entry, or is receiving treatment with oestrogens or non-steroid anti-androgens at the time of study entry

5. The patient has any condition rendering him unable to understand the nature, scope and possible consequences of the study
6. The patient has received any investigational drug therapy within 30 days prior to study entry, or is scheduled to receive such a drug during the study period
7. The patient is either scheduled to receive, receiving or anticipated to require any chemotherapy for prostate cancer or any other cancer during the period of his participation in the study
8. ECOG score greater than 2
9. Previous transurethral resection of the prostate (TURP)
10. Current indwelling urethral catheter (Patients performing intermittent self catheterisation are not excluded)
11. Prostate volume greater than 100 cc
12. Use of 5-alpha reductase inhibitors (Dutasteride, Finasteride) for less than 6 months
13. Patient is taking medication that is prohibited by the study protocol

Date of first enrolment
14/02/2011

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Royal Infirmary
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Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Industry

Funder Name
Ipsen Pharma (UK) - Research grant (ref: Y-97-52014-167)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	quality of life results presented at ASCO	20/02/2017	21/02/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes