

Effect of Decapeptyl® on prostate Volume pre-RadioTherapy

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

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

Contact name

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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

Primary study design

Interventional

Study design

Single-centre single-blind randomised active-controlled trial

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

Bristol

United Kingdom

BS2 8HW

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
Plain English results				No	Yes