ISRCTN72793878 https://doi.org/10.1186/ISRCTN72793878

# Effect of Decapeptyl® on prostate Volume pre-RadioTherapy

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

**EudraCT/CTIS number**
2008-007028-25

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

### 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 measure
Reduction in size of prostate as measured by trans rectal ultrasound

### Secondary outcome measures
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

### Overall study start date
03/01/2011

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### Target number of participants
72

### 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
England

United Kingdom

### Study participating centre
**Bristol Royal Infirmary**
Bristol

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# Sponsor information

### Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

### Sponsor details
Research and Innovation Department
University Hospitals Bristol NHS Foundation Trust
Level 3 Education Centre
Upper Maudlin Street
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BS2 8AE

### Sponsor type
Hospital/treatment centre

### Website
http://www.uhbristol.nhs.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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date
31/07/2019

## 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? |
|---|---|---|---|---|---|
| Plain English results | | | | No | Yes |
| 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 |