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Efficacy and safety of Decapeptyl® SR by subcutaneous injection in patients with a diagnosis of prostate cancer

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/05/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/09/2016	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Decapeptyl is a drug given to men with prostate cancer. Prostate cancer cells need the male hormone testosterone in order to grow and develop. Treatment with hormone suppression therapy reduces the level of testosterone in the body and by doing this reduces the number and size of prostate cancer cells. Decapeptyl (a trade name for a drug called Triptorelin) is a licensed hormone suppression treatment. It is given by an 'intramuscular' (IM) injection, which means an injection into muscle. The purpose of this study was to see if Decapeptyl could be administered by subcutaneous (SC) injection, an injection given into the skin, as well as by injection into muscle. If Decapeptyl could be given by SC injection as well as by IM injection patients would have more choice of injection sites and it would make self-administration of the injections easier.

Who can participate?
Men aged at least 18 and diagnosed with prostate cancer.

What does the study involve?
Men who take part in the study attend the outpatient clinic on 5 occasions over approximately 5 months. Two injections of Decapeptyl are given into the skin on the stomach area. Patients are checked at every visit to see if they had experienced any side effects, and blood tests are taken and checked to see if the levels of Prostate Specific Antigen and Testosterone fell as they would if the drug was given into the muscle. Patients are also asked questions to see if they had any problems such as pain or redness at the injection site.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Bristol Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
December 2007 to December 2010

Who is funding the study?
Ipsen Pharma (UK)

Who is the main contact?
Ms Katrina Hurley

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
2006-006595-38

Protocol serial number
4918

Study information

Scientific Title
A phase II, open-label, single-arm study to assess the efficacy and safety of Decapeptyl® SR (3 mg and 11.25 mg formulations) when administered by subcutaneous injection

Acronym
DISC

Study objectives
This is an open-label, single-arm trial designed to assess the efficacy, safety and tolerability of Decapeptyl® SR when administered by subcutaneous injection. Enrolled patients will be those who have a diagnosis of prostate cancer and for whom medical castration by means of androgen deprivation therapy is indicated. Each patient's participation in the trial will last up 5 months (including the screening period).

During the study, patients will receive one injection of Decapeptyl® SR 3 mg (the 1-month sustained release formulation) and one injection of Decapeptyl® SR 11.25 mg (the 3-month sustained-release formulation). The 3 mg injection will be administered at the study visit 2, on

day 0 (baseline) and the 11.25 mg injection will be administered one month later, at visit 3. Patients will have additional follow-up visits at month 2 and month 4 (end of study visit).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cornwall and Plymouth Research Ethics Committee (REC) approved on the 31/07/2007 (ref: 07/H0203/129)

Study design
Multicentre non-randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Renal and Urogenital, National Cancer Research Network; Subtopic: Renal and Urogenital (all Subtopics); Disease: Urogenital

Interventions
Decapeptyl® SR (3 mg and 11.25 mg) given subcutaneously.

Total duration of treatment: 4 months
Follow-up length: 5 months

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Decapeptyl® SR

Primary outcome(s)
The proportion of patients with serum testosterone levels of greater than or equal to 50 ng/dL 4 months after their first injection

Key secondary outcome(s))
The proportion of patients with serum testosterone levels of greater than or equal to 50 ng/dL 1 month after their first injection

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Patients must fulfil all of the following criteria in order to be included in the study:
1. The patient has given written (personally signed and dated) informed consent before starting any study-related procedure, which means any assessment or evaluation that would not have formed part of their normal medical care
2. The patient is male and is 18 years of age or older
3. The patient has a histologically or cytologically confirmed diagnosis of prostate cancer and meets the following criteria:
3.1. Stage T3 or T4, N (any), M (any) with a prostate specific antigen (PSA) greater than 5 ng/ml, or
3.2. Biochemical relapse following radical prostatectomy or radical radiotherapy for prostate cancer
4. Medical castration by means of luteinising hormone releasing hormone agonist (LHRHa) therapy is indicated for the patient
5. The patient has a life expectancy of at least 12 months
6. The patient is able and willing to comply with the requirements of the protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
Patients who fulfil any of the following criteria, will not be included in the study:
1. The patient has undergone bilateral orchidectomy
2. The patient is either scheduled to receive, receiving, or is anticipated to require any chemotherapy for prostate cancer, or any other cancer, during the period of his participation in the study
3. The patient is either scheduled to receive, or anticipated to require any surgical intervention for their prostate cancer during the period of his study participation
4. The patient has any condition that in the opinion of the Investigator may preclude the administration of subcutaneous Decapeptyl® SR injections
5. The patient has received treatment with any LHRHa within 1 year prior to study entry
6. The patient has a history of hypersensitivity to Decapeptyl® SR or CPA or to any of the excipients of Decapeptyl® SR or CPA
7. The patient has any contraindication to treatment with anti-androgens, including, but not limited to clinically significant abnormalities in liver function
8. The patient has been treated with oestrogens or steroid androgens within the 12 months prior to screening, or is receiving treatment with non-steroid anti-androgens at the time of the screening visit
9. The patient, in the opinion of the Investigator is at risk of serious complications in the event of

tumour flare (e.g., vertebral metastases threatening spinal cord compression, significant obstructive uropathy) on initiation of Decapeptyl® SR treatment, despite concomitant treatment with anti-androgens
10. The patient has any other condition that, in the opinion of the Investigator, might increase the risk to the patient or decrease the chance of obtaining satisfactory data needed to achieve the objective(s) of the study
11. The patient is likely to require treatment during the study with drugs that are not permitted by the study protocol
12. The patient has received any investigational drug, within 30 days prior to the study or is scheduled to receive such a drug during the study
13. The patient has a history of, or known current, problems with alcohol abuse
14. The patient has any mental condition rendering him unable to understand the nature, scope and possible consequences of the study
15. The patient has previously been enrolled in this study

Date of first enrolment
04/12/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Royal Infirmary
Department of Urology
Marlborough Street
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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)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration