

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/09/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
Ms Katrina Hurley

Contact details
Department of Urology
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Additional identifiers

EudraCT/CTIS number
2006-006595-38

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 to 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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

The proportion of patients with serum testosterone levels of greater than or equal to 50 ng/dL 1 month after their first injection

Overall study start date

04/12/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

Planned sample size: 50; UK sample size: 50

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

England

United Kingdom

Study participating centre

Bristol Royal Infirmary
Department of Urology
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation

University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details

Research and Development
Upper Maudlin Street
Bristol
England
United Kingdom
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)

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

02/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration