Phase II multi-centric, randomised, open-label, parallel-group study to assess the non-inferiority of Pamorelin® 11,25 mg SC injected versus Pamorelin® 11,25 mg IM injected in patients suffering from advanced prostate cancer

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Primary Study ObjectiveTo assess the non-inferiority of the 12-week triptorelin formulation Pamorelin® 11,25 mg administered via subcutaneous (SC) injection as compared to Pamorelin® 11,25 mg administered via registered intramuscular (IM) injection...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON29795

Source
ToetsingOnline

Brief title
Pamoject

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
localy advanced prostate cancer, prostate cancer

Research involving

Human

Sponsors and support

Primary sponsor: Ipsen Pharmaceuticals
Source(s) of monetary or material Support: Ipsen Farmaceutica

Intervention

Keyword: bio-equivalence, LHRH-analogue, prostate cancer

Outcome measures

Primary outcome

Primary Efficacy Variables:

Percentage of patients achieving a plasma testosterone level * 50 ng/dl (1,7

nmol/l) measured at week 24

Secondary outcome

Secondary Efficacy Variables:

Patient acceptability of the injection; the pain experienced during injection,

scored by means of a Visual Analogue Scale (VAS), measured at baseline and 12

weeks

Care giver acceptability of the administration of the injection by means of a

Visual Analogue Scale (VAS), at baseline and 12 weeks

Percentage of patients achieving a plasma testosterone level * 50 ng/dl (1,7

nmol/l) measured at week 12

Study description

Background summary

This study, involving 210 patients with prostatic adenocarcinoma is intended to

establish the non inferiority of triptorelin SR 11,25 mg administered via subcutaneous route every 12 weeks as compared to the registered intra-muscular administration every 12 weeks and should demonstrate the ability of this administration route to suppress testosterone below castrate levels at week 24. The subcutaneous administration route is less painful for the patient and aims an improvement in patient comfort with sustained efficiancy in comparison with the registered administration route.

Study objective

Primary Study Objective
To assess the non-inferiority of the 12-week triptorelin formulation Pamorelin® 11,25 mg administered via subcutaneous (SC) injection as compared to Pamorelin® 11,25 mg administered via registered intramuscular (IM) injection based on the percentage of patients presenting a testosterone level * 50 ng/dl at week 24.
Secondary Study Objectives
Overall patient acceptability of SC vs IM injection of Pamorelin® 11,25 mg
Overall caregiver acceptability of SC vs IM injection of Pamorelin® 11,25 mg
To assess the tolerability and safety of SC and IM injections of Pamorelin® 11,25 mg
To assess the non-inferiority of the 12-week triptorelin formulation Pamorelin® 11,25 mg administered via SC injection as compared to Pamorelin® 11,25 mg administered via standard IM injection based on the percentage of patients presenting a testosterone level * 50 ng/dl at week 12

Study design

Phase II multi-centric, randomised (1:1), open-label, parallel-group study

Intervention

Group A : Pamorelin® 11,25 mg administered as standard IM injection
Group B : Pamorelin® 11,25 mg administered as a SC injection

Study burden and risks

The burden for the patient participating in this trial consists of 3 blood collections for the evaluation of the testosteron level and 2 injections (SC or IM) for the administrations of the study medication.
It is possible that because of the administration of triptorelin the patient can experience a 'flare up' during the first four weeks of the therapy.
This event is developed because of a temporarily increase of the testosteron production. During the 'flare up' it is possible that the symptoms, the patient is experiencing due to his disease, become worse.
Because of the reduction of the testosteron level the patient can experience fatigue, weight gain, loss of mussle strenght, depression and reduction of

bone density.
Also local adverse events can be experienced from the injection.
Redness, pain, mussle pain (if intra muscular injection), development of haematoma at the injection site or at the injection site for blood collection.
Based on the text of risk and advantages the treatment presented in this study is deemed acceptable for the treatment of prostate cancer.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Written informed consent
Male patients aged 18 years and older
Histological proven prostate cancer, locally advanced or metastatic and scheduled to receive hormonal deprivation therapy.

Exclusion criteria

Hypersensitivity to Pamorelin or drugs with similar structure.
Was treated with other IMP within the last 30 days before study entry.
Has previously received a LHRH analogue, estrogens or a steroidal anti-androgen within the last year preceding the study.
Patient who underwent orchidectomy or is scheduled to receive an orchidectomy during the course of this study.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2007
Enrollment:	210
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Pamorelin® 11,25 mg
Generic name:	triptorelin pamoate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	31-07-2006
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2005-005058-31-NL
CCMO	NL11895.029.06