An Open-Label, Multi-Centre, Uncontrolled, Trial Investigating Degarelix One-Month Dosing Regimen Administered as Intermittent Androgen Deprivation (IAD) for One or More Cycles in Patients with Prostate Cancer Requiring Androgen Deprivation Therapy

Published: 29-08-2008
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Primary Objective - To evaluate the time to PSA >4 ng/mL during the first cycle of IAD after the end of an induction period with degarelix (7 monthly treatments) in prostate cancer patientsSecondary Objectives - To evaluate the time to PSA .4 ng/...

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

Summary

ID

NL-OMON38143

Source
ToetsingOnline

Brief title
FE200486 CS29

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Prostatic disorders (excl infections and inflammations)

Synonym

prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Ferring
Source(s) of monetary or material Support: Ferring Pharmaceuticals A/S

Intervention

Keyword: androgen, cancer, Degarelix, prostate

Outcome measures

Primary outcome

The main study parameters are median and between patient variability of time to PSA >4 ng/mL after 7 monthly injections of degarelix induction treatment.

Secondary outcome

Median and between patient variability of time to PSA >4 ng/mL in patient subgroups.

Median and between patient variability of time to return to testosterone >0.5 ng/mL (above castration level).

Median and between patient variability of time to return to age-adjusted lower limit of normal range or baseline testosterone level (whichever is first).

Percentage change in PSA from baseline to the last visit of the induction treatment period.

Serum levels of PSA and testosterone during the induction treatment and off-treatment periods.

Quality of Life as assessed by the EORTC QLQ-PR25 during the induction treatment and off- treatment periods.

Sexual function as assessed by the International Index of Erectile Function

(IIEF) scale during the induction treatment and off-treatment periods.

Frequency and severity of adverse events and clinically significant changes in

laboratory safety parameters.

Clinically significant changes in physical examinations, ECGs, vital signs and

body weight

Study description

Background summary

Degarelix is a gonadotrophin releasing hormone (GnRH) receptor blocker (antagonist). Degarelix is highly selective in binding to the GnRH receptor resulting in the suppression of pituitary gonadotrophins, leading to testosterone suppression.
Prostate cancer tissue contains clonal populations of testosterone dependent and independent cells. In the androgen dependent cells, testosterone and its metabolite dihydrotestosterone (DHT) stimulate cell proliferation via the androgen receptors. In the absence of hormones, the growth of these testosterone dependent cell populations will cease and result in a reduction of tumor mass.
The main focus of the efficacy evaluation in the clinical development program of degarelix is the ability to attain and sustain serum testosterone at or below castrate levels (serum testosterone level <=0.5 ng/mL). Based on previous clinical trials, a marketing authorisation application for degarelix 240/80 mg one-month dose regimen has been submitted to EMEA and FDA on February 27th 2008.

Study objective

Primary Objective - To evaluate the time to PSA >4 ng/mL during the first cycle of IAD after the end of an induction period with degarelix (7 monthly treatments) in prostate cancer patients
Secondary Objectives - To evaluate the time to PSA .4 ng/mL during the second and subsequent cycles of IAD after the end of an induction period with degarelix (7 monthly treatments).
To evaluate the time to PSA >4 ng/mL during the first cycle of IAD in patient sub-groups and to determine the time to return to age-adjusted lower limit of normal range or baseline level of testosterone during the first and subsequent

cycles of IAD after the end of an induction period with degarelix (7 monthly treatments).
To evaluate disease specific Quality of Life during the induction degarelix treatment and off-treatment periods during the first and subsequent cycles of IAD.
To evaluate sexual function during the induction degarelix treatment and off-treatment periods during the first and subsequent cycles of IAD.
To evaluate safety and tolerability during the induction degarelix treatment and off-treatment periods during the first and subsequent cycles of IAD.

Study design

An open label design without control group using degarelix as IAD for one or more cycles (7 monthly doses followed by a variable off-treatment period for each patient). A visit is scheduled on a monthly basis during the induction treatment period and every two months during the off-treatment period.

Intervention

Degarelix will be administered as deep s.c. injections in the abdominal region. A starting dose of 240 mg of degarelix (40 mg/mL) will be given on Day 0 as two 120 mg s.c. injections. Thereafter, 6 doses of 80 mg degarelix (20 mg/mL) will be given 28 days apart via single s.c. injections.

Study burden and risks

Each patient is expected to have 10-20 visits for a total duration of up to 31 months. Patients will have physical examination, urinalysis and ECG at first and last visit of the treatment period, and blood samples at each visit. The amount of blood taken per visit will be between 10 and 30 mL. Quality of Life questionnaire will be completed first and last visit of the treatment period and every 6 months during off-treatment period.
Treatment with degarelix is likely to be associated with side effects similar to those found with other treatments that reduce testosterone levels such as hot flushes, increased sweating, loss of sex drive, impotence, and infertility. Other side effects seen in the development phase of the trial drug include fatigue, urinary tract infection, dizziness, constipation, anaemia, and inflammation of the nasal part of the pharynx. Degarelix is well-tolerated at the injection sites, the most reported reactions are injection site pain and redness associated with the starting dose. Overall, the risks involved are primarily anticipated to be mild to moderate.

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

1. Has given written informed consent before any trial-related activity is performed. ;2. Has prostate cancer, and is in need of this type of treatment.

Exclusion criteria

1. Has had previous or is currently under hormonal treatment of prostate cancer. ;2. Is considered to be candidate for radical prostatectomy or radiotherapy. ;3. Has a history of severe uncontrolled asthma and/or other severe allergic reactions. ;4. Has hypersensitivity towards any component of degarelix. ;5. Has had cancer within the last five years except prostate cancer and some types of skin cancer. ;6. Has a severe disorder (other than prostate cancer) including but not limited to liver, biliary, renal, haematological, gastrointestinal,

endocrine, cardiac, neurological, or psychiatric disease, and alcohol or drug abuse or any other condition, as judged by the investigator.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2009
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Firmagon
Generic name:	Degarelix

Ethics review

Approved WMO Date:	29-08-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-12-2008
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-01-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-02-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-06-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-10-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-08-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-01-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-07-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-05-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-06-2012
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2008-003931-19-NL
CCMO	NL24043.042.08