An Open-Label, Multi-Centre, Extension Trial, Evaluating the Long-Term Progression-Free Survival of Degarelix or Goserelin Three-Month Dosing Regimens in Patients with Prostate Cancer Requiring Androgen Deprivation Therapy

Published: 23-11-2010
Last updated: 03-05-2024

To compare prostate-specific antigen (PSA) progression-free survival (PFS) failure rates during long-term treatment with 3-monthly subcutaneous (s.c.) injections of degarelix or goserelin in prostate cancer patients (PSA PFS failure is defined as...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON34559

Source
ToetsingOnline

Brief title
Ferring_CS35A

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
prostate cancer, prostate carcinomasosis

Research involving

Human

Sponsors and support

Primary sponsor: Ferring
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Androgen, Cancer, Deprivation, Prostate

Outcome measures

Primary outcome

Primary endpoint

* Hazard ration of PSA PFS failure rates during 3 years treatment between degarelix and goserlin.

Secondary outcome

Secondary endpoints

* Hazard ratio of PFS failure rates during 3 years' treatment between degarelix and goserelin

* Hazard ratio of PSA failure rates during 3 years' treatment between degarelix and goserelin

* Hazard ratio of the rates of introduction of additional therapy related to prostate cancer during 3 years' treatment between degarelix and goserelin

* Hazard ratio of mortality rates during 3 years' treatment between degarelix and goserelin

* Serum levels of testosterone and PSA over time.

* Hazard ratio of testosterone escape rates during 3 years' treatment between degarelix and goserlin

* Frequency and severity of adverse events

* Changes in alkaline phosphatase over time

* Clinically significant changes in laboratory safety parameters

* Clinically significant changes in physical examinations, ECG's, vital signs

and body weight.

Study description

Background summary

Prostate cancer is the most frequent cancer diagnosed in men. Degarelix is a gonadotrophin releasing hormone receptor blocker (GnRH) and is highly selective in binding to the GnRH receptor resulting in the suppression of pituitary gonadotrophins, leading to testosterone suppression.
This is an open-label trial extending the CS35 trial. The patients will continue to receive the same 3-monthly treatment as they received in the CS35 for 2 additional years after entering the extension phase.

Study objective

To compare prostate-specific antigen (PSA) progression-free survival (PFS) failure rates during long-term treatment with 3-monthly subcutaneous (s.c.) injections of degarelix or goserelin in prostate cancer patients (PSA PFS failure is defined as either PSA failure or death, whichever is first).

Study design

Open-label, multi-center, extension study

Intervention

Degarelix powder and solvent for suspension for s.c. injection: three-month dose of 480 mg degarelix.

Goserlin acetate (Zoladex) implant: three-month implant of 10,8 mg s.c.

Study burden and risks

Procedures during 2 years of study participation:

3 x weight & length
2 x physical examination
3 x ECG
5 x urine analysis
10 x blood sampling
10 x vital signs

Contacts

Public
Ferring

Kay Fiskers Plads 11
DK-2300 Copenhagen
Denmark
Scientific
Ferring

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Denmark

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients who complete the main trial (CS35) after the initiation of CS35A will be eligible for inclusion in the CS35A extension trial. Signed informed consent will be obtained before any trial-related activity is performed.

Exclusion criteria

Patients who complete the main trial (CS35) after the initiation of CS35A will be eligible for inclusion in the CS35A extension trial. Signed informed consent will be obtained before any trial-related activity is performed.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2010
Enrollment:	4
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Firmagon
Generic name:	Degarelix
Product type:	Medicine
Brand name:	Zoladex
Generic name:	Goserelin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-11-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-12-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2010-021434-55-NL
CCMO	NL34265.060.10