Phase III, open-label, multi-center study to assess the pharmacodynamic (PD), pharmacokinetic (PK) and safety of Zoreline 10.8 mg goserelin subcutaneous implant (Novalon) in male patients with prostate cancer

Published: 23-07-2015
Last updated: 20-04-2024

To assess the PD, PK and safety of the Zoreline 10.8 mg goserelin subcutaneous (SC) implant.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42816

Source
ToetsingOnline

Brief title
0080CA002

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate adenocarcinoma, prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Novalon S.A.
Source(s) of monetary or material Support: Novalon S.A.

Intervention

Keyword: prostate cancer, Zoreline

Outcome measures

Primary outcome

Primary variable:

Pharmacodynamics:

* The primary objective will be considered as achieved if the lower limit of the 2-sided 95% confidence interval (CI) on the responder rate is >=90%. A responder is defined as a subject who reached plasma testosterone levels below the castrate level (<=50 ng/dL) by Day 29 of Cycle 1 at the latest and maintained plasma testosterone levels below the castrate level (<=50 ng/dL) until Day 85 of Cycle 2 (end of treatment).

Secondary outcome

Secondary variables:

Pharmacodynamics:

* Plasma concentrations of testosterone including initial flare between Day 1 and Day 29 of Cycle 1, time to achieve castrate level, acute on chronic phenomenon (surge(s) at re-injection) between Day 2 and Day 4 of Cycle 2 and potential escape (surge) following the onset of suppression after the initial flare in Cycle 1 to Day 85 of Cycle 1 (pre-dose of Cycle 2) and from Day 8 until day 85 of Cycle 2 (end of treatment).

Pharmacokinetics:

* Plasma concentrations of goserelin

Safety:

* Occurrence of serious and non-serious adverse events.

Exploratory variables:

* Serum concentrations of luteinizing hormone (LH) and follicle-stimulating hormone (FSH)

* Serum concentrations of PSA.

* Responder rate considering a plasma testosterone concentration <=20 ng/dL as castrate level.

Performance of a novel syringe used to inject Zoreline 10.8 mg implant will be assessed through a questionnaire for the Investigators.

Study description

Background summary

This clinical study is designed to assess the PD, PK and safety of the Zoreline 10.8 mg goserelin subcutaneous (SC) implant, a generic version of Zoladex® 10.8 mg goserelin subcutaneous implant (AstraZeneca, United Kingdom) planned to be submitted under a hybrid application (Directive 2001/83/EC Art.10(3)), in male patients with prostate cancer. Zoreline implants are manufactured under responsibility of Novalon S.A., Belgium

Study objective

To assess the PD, PK and safety of the Zoreline 10.8 mg goserelin subcutaneous (SC) implant.

Study design

This is a phase III, open-label, multi-center study.

Intervention

Zoreline 10.8 mg goserelin subcutaneous implant (injected every 84 days on Day 1 of Cycle 1 and 2 (Day 85 of Cycle 1 is Day 1 of Cycle 2))

Study burden and risks

As Zoreline 10.8 mg is developed as a generic version of Zoladex 10.8 mg, with the
same dosage of active ingredient goserelin and same excipients as the marketed product, patients who participate in this studly will have access to treatment for their
prostate cancer which it is expected to exercises the same clinical effect as Zoladex
10.8 mg. The safety profile is also expected to be the same.

The burden from study required assessments include potential pain/inconvenience from blood draws, undergoing an ECG, the completion of a patient diary, and inconvenience of attending study required visits to the clinic (18 times). Patients will receive a travel reimbursement at 0.30 euro per kilometer and reimbursement of parking costs.

The results of the study may contribute to the availability of another (generic) treatment for prostate cancer in the future.

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. Males aged 18 years (inclusive) or above;2. Histologically confirmed prostate adenocarcinoma and indicated for androgen deprivation therapy (ADT). Previous prostatectomy and/or prostate radiotherapy is allowed.;3. Good physical and mental health as judged by the Investigator determined by medical history, physical examination, clinical laboratory and vital signs;4. Willing to give informed consent in writing;5. Willing and able to attend the scheduled study visits and to comply with the study procedures;6. Baseline testosterone level > 250 ng/dL;7. PSA level >= 4 ng/mL;Exception: for patients who have had previous prostatectomy and/or prostate radiotherapy, all PSA levels are allowed.;8. Life expectancy > 1 year;9. Body Mass Index between 18.5 and 35 kg/m2 inclusive;10. ECOG score of <=2

Exclusion criteria

1. Previous or current hormonal management of prostate cancer (surgical castration or other hormonal manipulation, including GnRH receptor agonists, GnRH receptor antagonists, anti-androgens, estrogens) within 6 months prior to the Screening visit;2. Scheduled for prostatectomy or radiotherapy during study period;3. ALT (SGOT) or AST (SGPT) >=2x upper limit of normal (ULN) ;4. moderate (stage 3B) or severe (stage 4 and 5) chronic kidney disease with an eGFR <45 mL/min/1,73m2;5. Has received an investigational drug within the last 28 days before the screening visit or longer if considered by the Investigator to possibly influencing the outcome of this trial ;6. History or presence of any malignancy other than treated squamous cell/basal cell carcinoma of the skin within the last five years;7. Have an unstable medical condition or chronic disease (including history of neurological [including cognitive], hepatic, renal, cardiovascular, gastrointestinal, pulmonary, or endocrine disease), or malignancy that could confound interpretation of the study at Investigator discretion;8. History of severe uncontrolled asthma, anaphylactic reactions, or severe urticarial and/or angioedema, and particularly, history of hypersensitivity towards any components of the

study drug;9. Other abnormal laboratory results which in the judgment of the Investigator would affect the patient's health or the outcome of the trial;10. Has an intellectual incapacity or language barrier precluding adequate understanding or co-operation

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):	26-10-2015
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Zoreline
Generic name:	goserelin

Ethics review

Approved WMO Date:	23-07-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	01-10-2015

Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	EUCTR2013-000799-14-NL
CCMO	NL54227.099.15