Less injections by androgen scrutinisation

Published: 01-05-2017
Last updated: 04-01-2025

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

Summary

ID

NL-OMON45500

Source
ToetsingOnline

Brief title
MIDAS

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: geen financiering beschikbaar;wordt verricht onder het reguliere arbeidscontract met het ziekenhuis

Intervention

Keyword: ADT, LHRH-agonists, Prostatic Neoplasms, testosterone-based dosing

Outcome measures

Primary outcome

Mean number of goserelin injections 10.8mg during the 24 months follow-up

period.

Secondary outcome

Secondary endpoints: difference in time to castrate refractory disease and

difference in treatment costs between the two strategies.

Study description

Background summary

Chemical or surgical castration is a key strategy in patients with locally advanced or metastatic prostate cancer. The goal is to eliminate gonadal testosterone production, so called castration. Currently, both chemical and surgical castration are considered equal modalities to achieve castration. Chemical castration is achieved by administering Luteinizing Hormone Releasing Hormone (LHRH) agonists on a regular basis. However, after prescribing LHRH agonists, physicians do not monitor the testosterone levels routinely. Moreover, current dosing regimens are manufacturer-recommended.
Several studies have shown that serum testosterone levels remain longer at or below castrate levels when 3-monthly depot injections of LHRH agonists are administered [3 - 7]. This opens opportunities for a personalized way of dosing LHRH agonists depending on the testosterone level. However, in the performed testosterone-based dosing studies only the LHRH agonist leuprorelin has been investigated [3 - 4]. The current study will be initiated to evaluate a testosterone-based dosing regimen with depot injections of goserelin 10.8 mg for all eligible patients as well as subgroups of patients.
Based on the performed testosterone-based dosing studies with leuprorelin we expect that the dosing interval of depot injections of goserelin 10.8 mg can be prolonged to 5 or 6 months.
An effective personalized treatment regimen will probably lower the treatment burden (for patients) and treatment costs (for society) while treatment goals

are still achieved.

Study objective

The primary objective of this study is to determine the possibility to extend the dosing interval of goserelin 10.8 mg with a testosterone-based dosing regimen compared to regular treatment with 3-monthly based goserelin 10.8 mg injections.
This will be achieved by estimating the difference in the number of LHRH agonist injections in the testosterone based regimen compared to regular treatment with 3-monthly based goserelin 10.8 mg injections.

The secondary objectives are:
* To determine whether a testosterone-based dosing regimen of goserelin 10.8 mg is cost-saving compared to regular treatment with a 3-monthly based goserelin 10.8 mg injection.
* To estimate the difference in the time to castrate refractory disease in the testosterone based regimen compared to regular treatment with 3-monthly based goserelin 10.8 mg injections.
Collected data will also be used to o develop a pharmacokinetic model for goserelin in MWPharm.

Study design

This study is a randomized, controlled trial. Patients will be randomized to 1) treatment as usual being 3-monthly depot injections of goserelin 10.8 mg; 2) treatment with a testosterone-based regimen in a 1:2 fashion.

Intervention

Control group: Patients treated with regular 3-monthly based goserelin 10.8 mg injections, regardless of testosterone level.

Study group: Patients will be treated according to the following algorithm.

Algorithm for testosterone-based treatment
Approximately 11 weeks after each depot injection of goserelin 10.8 mg blood levels of testosterone will be measured. When the following rule applies, a depot injection of goserelin 10.8 mg is injected subcutaneously into the anterior abdominal wall at 12 weeks:

A. an increase of more than 0.5 nmol/L from the nadir (the lowest testosterone achieved during castration)
OR
B. the testosterone level is above 1.2 nmol/L.

When the testosterone level does not meet one of the abovementioned requirements, goserelin treatment will be postponed, blood levels of testosterone will be measured again after four weeks (at approx. week 15) and according to the described algorithm the next depot injection of goserelin 10.8 mg is given or again postponed with 4 weeks. This cycle will continue for every patient in the study group as long as the testosterone level meets none of the described requirements.

Study burden and risks

For the control group, there is no additional risk.

For the study group, study participation not only implies more frequent blood sampling. It also implies that patients most likely will receive less depot injections of goserelin 10.8 mg and probably have a lower burden of the treatment due to the reduction of injections, assuming the testosterone-based dosing regimen is effective in extending the dosing interval.

The risk for complications due to depot injections of goserelin 10.8 mg and the risk for side-effects is not affected by this study.

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

* Informed consent
* Male > 18 years
* Diagnosed with prostate cancer with a clinical indication for ADT (*2 years or permanently)
* Patients can be included before the first injection of goserelin 10.8mg and in the first two months after the first injections of goserelin 10.8 mg.

Exclusion criteria

* Patients receiving anti-androgens (excluding bicalutamide for 4 weeks around the first LHRH agonist)
* Patients with a history of hypersensitivity to LHRH agonists
* Patients not able to visit hospital*s laboratory for blood sampling

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-08-2017

Enrollment:	42
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-01-2018
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

ID: 20372
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60691.101.17

Study results

Date completed:	01-05-2018

Results posted:	28-11-2018
Actual enrolment:	19

First publication
28-11-2018