Less injections by androgen scrutinisation

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20372

Bron
Nationaal Trial Register

Verkorte titel
MIDAS

Aandoening

Prostate Cancer, LHRH-agonists, androgen deprivation therapy, ADT, testosterone-based dosering

Prostaat kanker, LHRH-agonisten, androgeen deprivatie therapie, ADT, testosteron gebaseerd doseren

Ondersteuning

Primaire sponsor: Franciscus Gasthuis, Rotterdam
Overige ondersteuning: fonds = verrichter = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mean number of goserelin 10.8mg injections per patient during follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

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 3monthly depot injections of LHRH agonists are administered. 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. 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.

Doel van het onderzoek

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 during 24 months follow-up.

Onderzoeksopzet

Control group: once every 3 months

Intervention group: dependent on the testosterone levels in the patients

Onderzoeksproduct en/of interventie

Extending the dosing interval of goserelin 10.8 mg injections

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2017
Aantal proefpersonen:	42
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-06-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45500
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6353
NTR-old	NTR6537
CCMO	NL60691.101.17
OMON	NL-OMON45500

Resultaten