The effects of neoadjuvant hormonal therapy on the course of PSA and testosterone in patients with low and intermediate risk prostate carcinoma (NEO-ONE)

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To assess the effects of 3-month NHT on the 3-year course of PSA and testosterone in patients treated with BT for low-intermediate risk clinically localized prostate carcinoma. In addition, we would like to assess the effects of 3-month NHT on...

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

Summary

ID

NL-OMON39212

Source
ToetsingOnline

Brief title
NHT influence on PSA and testosterone after brachytherapy (NEO-ONE)

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
prostate carcinoma; prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: TweeSteden ziekenhuis
Source(s) of monetary or material Support: Astella s Europe (London),Astellas Pharma

Intervention

Keyword: brachytherapy, maximal androgen blockage, PSA, testosterone

Outcome measures

Primary outcome

Levels of PSA and testosterone over the 3-year follow-up period;

Secondary outcome

change in prostate volume+ other important variables: age, urinary complaints,

complications, events.

Study description

Background summary

Short-term neoadjuvant hormonal therapy (NHT; i.e. androgen blockage) preceding brachytherapy for low-intermediate risk clinically localized prostate cancer (BT) is used successfully to downsize the prostate to make seed implantation possible. However, NHT also seems to affect PSA levels in these patients, but this has not been tested before in a randomized clinical trial. In addition, no information is present on the effects of short-term androgen blockage on long-term post-BT testosterone levels.

Study objective

To assess the effects of 3-month NHT on the 3-year course of PSA and testosterone in patients treated with BT for low-intermediate risk clinically localized prostate carcinoma.
In addition, we would like to assess the effects of 3-month NHT on prostate volume.

Study design

This is an unblinded, randomised controlled clinical trial.

Intervention

The treatment group is given androgen blockage using Eligard 22.5 mg once and Bicalutamide 50 mg daily for the duration of three months preceding BT. The control group will receive BT immediately.

Study burden and risks

Preparatory and follow-up activities coincide with regular medical care. The only additional procedure is a transrectal ultrasound examination, this will pose a limited burden on some of the participating patients (only in the centers that agree to perform this additional ultrasound). In general, it is not expected that the current study poses any additional risks. Based on our previous observational study, we expect beneficial effects of 3-month NHT treatment on quality of life, urinary complaints and PSA levels post-BT.

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

These are the inclusioncriteria:
Patients with low and intermediate risk prostate cancer (according to Dutch guidelines)
prostate volume between 35 and 55 cc
a life expectancy of at least 10 years
written informed consent

Exclusion criteria

These are the exclusion criteria:
Contra-indication for BT
use of hormone suppressive therapy in the past or surgical castration.
use of 5 alfa reductase in the last 6 months
use of estrogens
cognitive impairments
negative decision for study participation by the hospitals* urology-radiotherapy meeting
kidney or liver dysfunction
history of myocardial infarction with present symptoms or CAD-induced heart failure

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: Pending
Start date (anticipated): 01-02-2012

Enrollment:	400
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Casodex 50 mg
Generic name:	bicalutamide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Eligard 22,5 mg
Generic name:	leuprorelide acetate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-11-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	13-12-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-09-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-12-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-01-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	EUCTR2011-004749-41-NL
CCMO	NL34027.028.11