Androgen Deprivation therapy for Oligo-recurrent Prostate cancer in addition to radioTherapy

Published: 26-11-2019
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This study has been transitioned to CTIS with ID 2024-511252-41-00 check the CTIS register for the current data. The aim of the current study is to extend the time to develop new disease progression in prostate cancer patients with recurrent disease...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52631

Source
ToetsingOnline

Brief title
ADOPT

Condition

- Other condition

Synonym
hormone, radiotherapy

Health condition

prostaat kanker

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Koningin Wilhelmina Fonds

Intervention

Keyword: Androgen Deprivation, Oligo-recurrent, prostate cancer

Outcome measures

Primary outcome

The primary goal of this project is to test the hypothesis that the addition of ADT to MDRT in well-chosen PCa patients with oligo-metastatic disease (OM) prolongs metastasis progression-free survival (MPFS) compared to radiotherapy alone.

Secondary outcome

The secondary goal is to gain more insight into the sensitivity of the PSMA-PET/CT or PSMA-PET/MRI for the detection of (oligo) metastases due to low PSA levels. For the latter, the location and size of the tumor causing secondary biochemical progression, as determined from the PSMA-PET/CT or PSMA-PET/MRI follow-up, will be assessed by comparing the PSMA scans before and after treatment. Furthermore, the quality of life of patients in both arms is examined.

other secoundary endpoints:

- 3 years PSA progression

- Start of 2nd line treatment

- Start 2nd MDRT treatment for new (progressive) oligo-metastases

- Acute and late toxicity (late toxicity up to 3 years)

- Clinical progression-free survival

- Quality of life

- Progression pattern

- Time to start of palliative ADT

- Time to castration-resistance

- Disease-specific and overall survival

- Sensitivity of the imaging modality (PSMA-PET/CT or PSMA-PET/MRI) for

patients receiving MDRT

- Predictive biomarkers

Study description

Background summary

When irradiating primary prostate cancer (in patients without metastases), it is known that the addition of short-term hormonal therapy to radiotherapy increases the chance of healing. Therefore, this study investigates whether the addition of short-term hormonal therapy to radiotherapy on the metastases improves the risk of long-term disease control

Study objective

This study has been transitioned to CTIS with ID 2024-511252-41-00 check the CTIS register for the current data.

The aim of the current study is to extend the time to develop new disease progression in prostate cancer patients with recurrent disease in the form of limited metastases (<5) and in some cases possibly even cure by adding 6 months of ADT to radiotherapy. improvement of metastases progression free survival.

Study design

This is a multicentre, randomized study. A total of 280 patients will participate in this study, equally divided between both study groups.

Intervention

Metastases direct radiotherapy to all visible metastases in both arm, 6 months ADT in the experimental arm.

Study burden and risks

all appointments will, where possible, be combined with already scheduled appointments in the hospital. Possible side effects of ADT in the experimental arm while the positive influence is not yet proven. fill out the questionnaires will take 30-45 minute for each control time point.

Contacts

Public
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Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Histologically proven initial diagnosis of adenocarcinoma of the Prostate.
2. Biochemical recurrence of prostate cancer following primary local prostate treatment (radical prostatectomy, primary radiotherapy or radical prostatectomy +/- prostate bed adjuvant salvage radiotherapy) according to the EAU guidelines 2018. BCR after surgery: PSA >= 0.1ng/ml. BCR after radiotherapy: PSA nadir +2 ng/ml or 3 consequent rises in PSA level (after exclusion of possible bounce effect).
3. Minimal 1 lesion and maximum 4 lesions (bone + lymph nodes) in total, without evidence of visceral metastases.
a. Nodal relapse (N1) in the pelvis on PSMA-PET scan with a maximum of 4 positive lymph nodes. The upper limit of the pelvis is defined as the aortic bifurcation.
b. Nodal relapse (M1a) on PSMA-PET scan above the aortic bifurcation with a maximum of 3 positive lymph nodes.
c. Bone relapse on PSMA-PET scan with a maximum of 3 lesions.
d. Combination of a, b, c with a maximum of 4 metastases.
4. Age >= 18 years.
5. PSMA-PET/CT scan or PSMA-PET/MRI within 60 days prior to randomization.
6. PSA < 10 ng/ml.
7. In case of chronic use of finasteride the PSA value should be < 5 ng/ml.
8. WHO performance state 0-2.
9. Signed informed consent prior to registration/randomization.

Exclusion criteria

1. Visceral metastases.
2. PSA >= 10 ng/ml.
3. PSA-doubling time <= 3 months.
4. ADT or chemotherapy for recurrent PCa.
5. Testosterone < 1.7 nmol/l.
6. Painful metastases needed pain medication (> level 1 pain medication) .
7. Invasive active cancers other than superficial non-melanoma skin cancers.
8. Inability or unwillngness to understand the information on trial-related topics, to give informed consent or to fill out QoL questionnaires.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-03-2020
Enrollment:	280
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Eligard
Generic name:	leuprorelin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-11-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-02-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	28-05-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-06-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-07-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-04-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-05-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-07-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-06-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-07-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EU-CTR	CTIS2024-511252-41-00
EudraCT	EUCTR2019-003177-26-NL
CCMO	NL70897.042.19