Evaluation of 18F-FDHT PET/CT as a predictor of response in patients with metastasized castration-resistant prostate cancer to be treated with enzalutamide.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20629

Source
Nationaal Trial Register

Brief title
FuTuRe

Health condition

Castration-resistant prostate cancer

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Center for Translational Molecular Medicine

Intervention

Outcome measures

Primary outcome

Diagnostic accuracy of 18F-FDHT PET/CT as a predictor of treatment response

Secondary outcome

Comparison of 'treatment response and clinical survival endpoints' versus 'no treatment response and clinical survival endpoints'

Study description

Background summary

Worldwide prostate cancer is the second most frequently diagnosed cancer in men. While localized prostate cancer can be treated with curative intent, metastasized prostate cancer has palliative treatment options only. Endocrine deprivation therapy is the mainstay of treatment for patients with metastasized prostate cancer. In the end, prostate cancer progresses in the majority of patients because of progressive tumor growth despite endocrine deprivation therapy: castration-resistant prostate cancer (CRPC). As CRPC progresses, approximately 90% of patients will develop bone metastases, in contrast to lymph node metastases which develop in 20% to 25% of patients. The determination of response to treatment in patients with CRPC is predominantly plagued by the presence of non-measurable bone metastases. Positron Emission Tomography (PET) is emerging as a promising imaging modality to evaluate treatment options and therapeutic response timely, objectively and quantitatively. 16β-[18F]-fluoro-5α-dihydrotestosterone (18F-FDHT) images the androgen receptor with high binding affinity and selectivity. It is expected that 18F-FDHTPET/CT can give an indication of success or failure early in the treatment course as part of clinical management or within the context of clinical trials. Timely response management may adjust the duration of individual treatment according to its success. This is where the FuTuRe trial comes in. The primary objective is to evaluate 18F-FDHT PET/CT as a predictor of response in patients with CRPC who are to be treated with enzalutamide.

Study objective

18F-FDHT PET/CT is expected to be a predictor of response in patients with metastasized castration-resistant prostate cancer to be treated with enzalutamide

Study design

Start 18F-FDHT PET/CT at baseline (prior to treatment), start enzalutamide at baseline, 18F-FDHT PET/CT after 4 weeks of treatment, follow-up visits on a monthly basis during the first year of the trial, afterwards once a quarter

Intervention

Enzalutamide

Contacts

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Eligibility criteria

Inclusion criteria

Main inclusion criteria:

1. Age 50 or older.

2. Histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features.

3. Ongoing androgen deprivation therapy with a gonadotropin-releasing hormone analogue or bilateral orchidectomy.

4. Progressive disease despite androgen deprivation therapy as defined by rising PSA levels or progressive soft tissue or bone disease.

5. Metastatic disease documented by bone lesions on bone scan or by measurable soft tissue disease by CT

6. No prior cytotoxic chemotherapy for prostate cancer.

7. Asymptomatic or mildly symptomatic from prostate cancer.

8. Written informed consent.

Exclusion criteria

Main exclusion criteria:

1. Severe concurrent disease, infection, or co-morbidity that, in the judgment of the investigator, would make the patient inappropriate for enrollment.

2. Known or suspected brain metastasis or active leptomeningeal disease.

3. History of another malignancy within the previous 5 years other than curatively treated non-melanomatous skin cancer.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-05-2014
Enrollment:	60
Type:	Unknown

Ethics review

Positive opinion

Date:	23-07-2013
Application type:	First submission

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
NTR-new	NL3919
NTR-old	NTR4086
Other	: FuTuRe
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A