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

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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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Anders |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON20629

**Bron**
Nationaal Trial Register

**Verkorte titel**
FuTuRe

**Aandoening**

Castration-resistant prostate cancer

### Ondersteuning

**Primaire sponsor:** University Medical Center Groningen
**Overige ondersteuning:** Center for Translational Molecular Medicine

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

Enzalutamide

# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Anders |
| (Verwachte) startdatum: | 01-05-2014 |
| Aantal proefpersonen: | 60 |
| Type: | Onbekend |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 23-07-2013 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3919 |
| NTR-old | NTR4086 |
| Ander register | : FuTuRe |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A