

Shared decision making in patients with Castration-Resistant Prostate Cancer

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The use of a web-based decision aid with value clarification exercises will improve patients' knowledge and will give patients realistic expectations of risks and benefits. Addition of the G8 (frailty instrument) and the Timed Up and Go-test as...

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

Samenvatting

ID

NL-OMON24989

Bron

NTR

Verkorte titel

SDM CRPC

Aandoening

Shared decision making, decision aid, prostate cancer, CRPC

Ondersteuning

Primaire sponsor: Elisabeth- TweekSteden Ziekenhuis

Postbus 90151

5000 LC Tilburg

Overige ondersteuning: KWF Kanker Bestrijding

Delfland 17

1062 EA Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Objective knowledge

- Informed choice

Toelichting onderzoek

Achtergrond van het onderzoek

We will conduct a stepped wedge randomized controlled trial. Each hospital will start as control (standard care) and will switch randomly to the implementation of the decision aid at consecutive time points. The effectiveness of the decision aid will be assessed with questionnaires before and after implementation. Participants are asked to complete a questionnaire at four different points in time: shortly after being diagnosed (T0 = baseline), at the point of decision making (T1), and at follow up 3 and 6 months.

Doel van het onderzoek

The use of a web-based decision aid with value clarification exercises will improve patients' knowledge and will give patients realistic expectations of risks and benefits. Addition of the G8 (frailty instrument) and the Timed Up and Go-test as supportive screening tools will help clinicians to recognize frail patients who might require adapted treatment.

Onderzoeksopzet

The effectiveness of the decision aid will be assessed with questionnaires before and after implementation. Participants are asked to complete a questionnaire at four different point in time: shortly after being diagnosed (T0 = baseline), at the point of decision making (T1), and at follow up 3 and 6 months.

Onderzoeksproduct en/of interventie

Decision aid with value clarification exercise

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Men that are newly diagnosed with CRPC. CRPC is defined as any cancer progression under maximal hormonal treatment with anti-androgens and/or LHRH agonist or antagonist (when three consecutive rises of PSA are observed at castrate serum levels of testosterone (< 50 ng/dL or < 1.7 nmol/L) and/or progression of osseous lesions is shown))
- Patients are eligible for at least two treatment options
- Patients have to be able to make use of a computer with internet-access in order to make use of the web-based decision aid
- Patients have to be able to complete a Dutch questionnaire

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- In the case of a second opinion the patient will not be included if the first opinion was obtained in one of the other involved hospitals and vice versa

- Patients who do not have sufficient knowledge of the Dutch language

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	168
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	20-04-2017
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	NL6223
NTR-old	NTR6379
Ander register	METZ Brabant/16.280 : NW2016-55

Resultaten