Shared decision making in patients with Castration-Resistant Prostate Cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24989

Source
NTR

Brief title
SDM CRPC

Health condition

Shared decision making, decision aid, prostate cancer, CRPC

Sponsors and support

Primary sponsor: Elisabeth- TweeSteden Ziekenhuis
Postbus 90151
5000 LC Tilburg
Source(s) of monetary or material Support: KWF Kanker Bestrijding
Delfland 17
1062 EA Amsterdam

Intervention

Outcome measures

Primary outcome

- Objective knowledge

- Informed choice

Secondary outcome

- Correlation between G8 score and treatment decision

- Correlation between TUG-test and treatment decision

- Quality of life

- Anxiety

- Value clarification

- Satisfaction with decision making, information and treatment

- Preparation for decision making

- Healthcare providers' evaluation of decision aid

- Partner involvement in SDM

- Treatment outcome (e.g. dose reductions, treatment delays, treatment discontinuation, treatment switch, and death)

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

Decision aid with value clarification exercise

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	168
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-04-2017
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	NL6223
NTR-old	NTR6379
Other	METZ Brabant/16.280 : NW2016-55

Study results