

Patient involvement in the choice between surgery and radiation for prostate cancer: what about regret?

No registrations found.

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

Summary

ID

NL-OMON22360

Source

Nationaal Trial Register

Brief title

PITCH

Health condition

prostate cancer
prostaatkanker

Sponsors and support

Primary sponsor: Dutch Cancer Society (KWF)

Source(s) of monetary or material Support: Dutch Cancer Society (KWF)

Intervention

Outcome measures

Primary outcome

- Process regret

- Option regret
- Outcome regret

Secondary outcome

- Patient preferences
- Reasons underlying these preferences
- Anxiety and Depression
- Health-related Quality of Life

Study description

Background summary

For primary localized prostate cancer different treatment options are available. The most frequently applied treatments are radical prostatectomy, external beam radiation therapy and brachytherapy. These treatments yield comparable results for tumor control, but they differ strongly in the procedure and their profile of side effects. The effect of involving patients into this treatment choice by means of a decision aid is the topic of this study.

Study objective

We hypothesise that regret is affected by adverse outcomes of the cancer treatment and not by patient involvement in the treatment choice.

Study design

- Baseline (before information on treatments)
- Pre-treatment (after information)
- 6 months after treatment choice
- 12 months after treatment choice

Intervention

The control group will receive usual care, i.e. the physician will discuss the options with the patients.

The intervention group will receive usual care plus structured information on the risks and benefits of the different treatment options by means of a purpose-built decision aid (DA) presented by a researcher. The use of DAs has been shown to increase the level of patient participation in treatment decisions.

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary localized prostate cancer (T1T2)

Exclusion criteria

1. Contra-indication for surgery
2. Aged over 70 years
3. Mental or cognitive problems
4. Inadequate knowledge of Dutch language

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion	
Date:	02-06-2008
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	NL1288
NTR-old	NTR1334
Other	: KWF 2007-3809
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A