

Patient involvement in prostate cancer treatment decisions

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/11/2007	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Dutch Cancer Society 2001-2379; NTR63

Study information

Scientific Title

Study objectives

How many and which patients want to choose their own radiation dose?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee CWOM number 0012-0284. Ethics approval date 16 March 2001.

Primary study design

Interventional

Study design

Non randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Control group is usual care (150 patients). Intervention group is usual care plus decision aid (150 patients).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary outcome measure is choice acceptance. At the end of the interview, the patient is asked whether he wants to choose one of the two treatment options, or whether he wants to leave the decision to the physician. The response to this question is choice acceptance. Choice acceptance is confirmed by telephone 2 days later. This measure is obtained about 10 days after the first consultation.

Key secondary outcome(s)

1. Substitute preferences of physicians
2. Quality of life measures
3. Decision evaluation measures
4. Coping measures
5. Knowledge measures
6. Treatment preferences

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Patients with prostate cancer referred for radiotherapy with curative intent are eligible.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

Key exclusion criteria

Labile personality structure, as assessed by the physicians, and lack of understanding of the Dutch language.

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Radboud University Nijmegen MC

Nijmegen

Netherlands

6500 HB

Sponsor information**Organisation**

Dutch Cancer Society (The Netherlands)

ROR

<https://ror.org/0368jnd28>

Funder(s)

Funder type

Charity

Funder Name

Dutch Cancer Society

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	20/07/2007		Yes	No