ISRCTN97145188 https://doi.org/10.1186/ISRCTN97145188

Patient involvement in prostate cancer treatment decisions

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr PFM Stalmeier

Contact details
Radboud University Nijmegen MC
MTA 138
PO Box 9101
Nijmegen
Netherlands
6500 HB
+31 (0)24 3610592
p.stalmeier@mta.umcn.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Non randomised controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

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

Overall study start date
01/01/2001

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

Age group
Not Specified

Sex
Male

Target number of participants
300

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)

Sponsor details
PO 75508
Amsterdam
Netherlands
1070 AM
+31 (0)20 5700500
rc@kwfkankerbestrijding.nl

Sponsor type
Charity

ROR
https://ror.org/0368jnd28

Funder(s)

Funder type
Charity

Funder Name
Dutch Cancer Society

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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