'PRIAS: Prostate cancer Research International: Active Surveillance - guideline and study for the expectant management of localized prostate cancer with curative intent'.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22061

Source
Nationaal Trial Register

Brief title
PRIAS

Health condition

Prostate cancer, overdiagnosis, overtreatment, active surveillance

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam.
Source(s) of monetary or material Support: Prostate Cancer Research Foundation (SWOP) Rotterdam, The Netherlands.

Intervention

Outcome measures

Primary outcome

Treatment free survival.

Secondary outcome

Prostate cancer specific and overall mortality.

Study description

Background summary

The incidence of prostate cancer has been rising over the last two decades, while the absolute mortality has remained stable. The proportion of men dying WITH prostate cancer instead of FROM prostate cancer has therefore increased.
A so called active surveillance strategy of selecting prostate tumors with a favorable prognosis, withholding radical treatment but instead monitoring the tumor with the option of curative treatment at the moment of progression, is indicated in a large proportion of the newly diagnosed prostate cancer.
Our international, protocol based, observational study aims to prospectively collect evidence for this stratregy, by applying a strcit protocl of inclusion and followcriteria.

Study objective

Early prostate cancer may safely be managed with an active surveillance strategy, avoiding overtreatment and the risk of resulting side effects.

Study design

Yearly analyses are being performed.

Intervention

None, observational study.

Contacts

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Eligibility criteria

Inclusion criteria

1) Histologically proven adenocarcinoma of the prostate.
2) Men should be fit for curative treatment.
3) PSA-level at diagnosis ≤ 10 ng/mL.
4) PSA density (PSA D) less than 0.2.
5) Clinical stage T1C or T2.
6) Gleason score 3+3=6.
7) One or 2 biopsy cores invaded with prostate cancer:
a.
If an MRI, including targeted biopsies on positive lesions, is done at inclusion, there is no limit in the number of positive cores (that is, more than two, and no limit in the % of cancer present in the cores).
b.
If saturation biopsies (either transperineal or transrectal) are done 15% of the cores can be positive with a maximum of 4. (i.e. <20 cores 2 cores can be positive (standard), 20-26 cores 3 cores can be positive, >26 cores 4 cores can be positive) (all other inclusion criteria still apply).
8) Participants must be willing to attend the follow-up visits.

Note: Patients with biopsy Gleason score 3+4 can be followed outside the actual PRIAS protocol.
The patient should be at least 70 years old and should have evidence of limited disease (maximum 10% tumor involvement per biopsy core, maximum 2 cores positive).
Risk reclassification is defined as any upgrading in Gleason score and/or more than 2 positive cores at repeat biopsy.

Exclusion criteria

1) Men who can not or do not want to be radiated or operated.
2) A former therapy for prostate cancer.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2006
Enrollment:	2000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-03-2009
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	NL1622
NTR-old	NTR1718
Other	MEC ErasmusMC : 2004-339
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
Prospective validation of active surveillance in prostate cancer: the PRIAS study.
van den Bergh RCN, Roemeling S, Roobol MJ, Roobol W, Schröder FH, Bangma CH.
Eur Urol. 2007 Dec;52(6):1560-3. PMID: 17532115.

The Prostate cancer Research International: Active Surveillance study.
Bangma CH, Bul M, Roobol M.
Curr Opin Urol. 2012 May;22(3):216-21. doi:
10.1097/MOU.0b013e328351dcc7. Review.
PMID:22453333

Active surveillance for low-risk prostate cancer worldwide: the PRIAS study.
Bul M, Zhu X, Valdagni R, Pickles T, Kakehi Y, Rannikko A, Bjartell A, van der Schoot DK, Cornel EB, Conti GN, Boevé ER, Staerman F, Vis-Maters JJ, Vergunst H, Jaspars JJ, Strölin P, van Muilekom E, Schröder FH, Bangma CH, Roobol MJ.
Eur Urol. 2013 Apr;63(4):597-603. doi:
10.1016/j.eururo.2012.11.005. Epub 2012 Nov 12.
PMID:23159452

A Decade of Active Surveillance in the PRIAS Study: An Update and Evaluation of the Criteria Used to Recommend a Switch to Active Treatment.
Bokhorst LP, Valdagni R, Rannikko A, Kakehi Y, Pickles T, Bangma CH, Roobol MJ; PRIAS study group..

Eur Urol. 2016 Dec;70(6):954-960. doi:
10.1016/j.eururo.2016.06.007. Epub 2016 Jun 19.
PMID:27329565

Complications after prostate biopsies in men on active surveillance and its effects on receiving further biopsies in the Prostate cancer Research International: Active Surveillance (PRIAS) study.
Bokhorst LP, Lepistö I, Kakehi Y, Bangma CH, Pickles T, Valdagni R, Alberts AR, Semjonow A, Strölin P, Montesino MF, Berge V, Roobol MJ, Rannikko A.
BJU Int. 2016 Sep;118(3):366-71. doi: 10.1111/bju.13410. Epub 2016 Feb 12.
PMID:26765682

Compliance Rates with the Prostate Cancer Research International Active Surveillance (PRIAS) Protocol and Disease Reclassification in Noncompliers.
Bokhorst LP, Alberts AR, Rannikko A, Valdagni R, Pickles T, Kakehi Y, Bangma CH, Roobol MJ; PRIAS study group..
Eur Urol. 2015 Nov;68(5):814-21. doi: 10.1016/j.eururo.2015.06.012. Epub 2015 Jun 29.
PMID:26138043

