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

Gepubliceerd: 11-03-2009 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22061

Bron
Nationaal Trial Register

Verkorte titel
PRIAS

Aandoening

Prostate cancer, overdiagnosis, overtreatment, active surveillance

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam.
Overige ondersteuning: Prostate Cancer Research Foundation (SWOP) Rotterdam, The Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Treatment free survival.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Yearly analyses are being performed.

Onderzoeksproduct en/of interventie

None, observational study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2006
Aantal proefpersonen:	2000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1622
NTR-old	NTR1718
Ander register	MEC ErasmusMC : 2004-339
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
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