

## PRIAS: Prostate cancer Research International: Active Surveillance

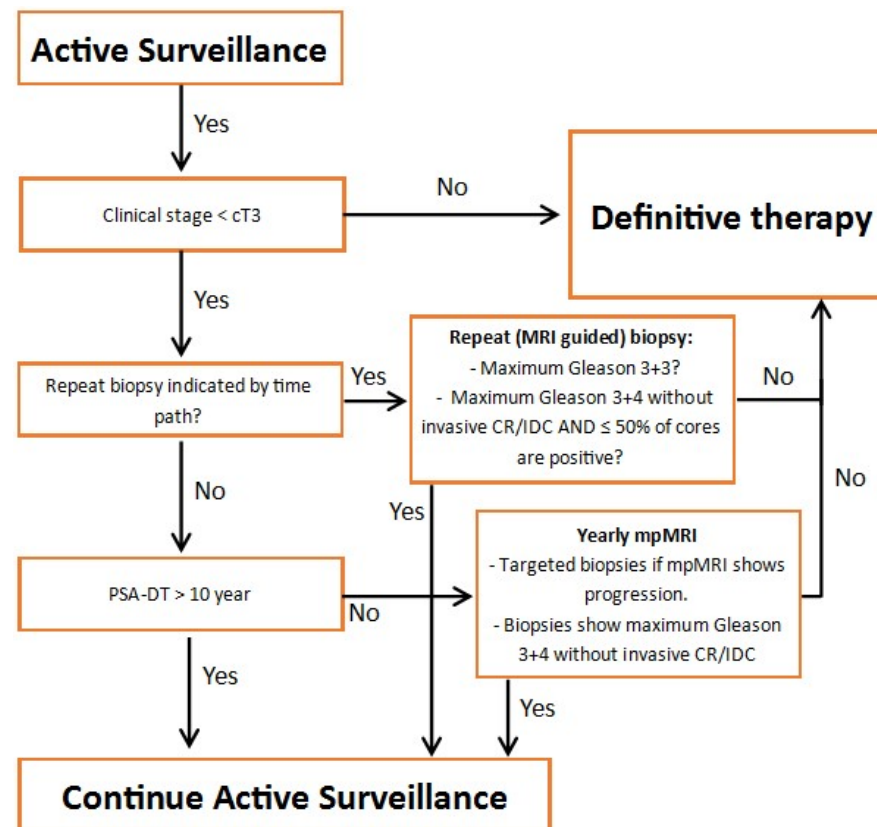
### Inclusion criteria:

- 1) Histologically proven adenocarcinoma of the prostate.
- 2) Men should be fit for curative treatment.
- 3) PSA level at diagnosis  $\leq 10$  ng/mL, or  $\leq 20$  ng/mL if MRI is used at diagnosis or during follow up.
- 4) PSA density (PSA-D) less than 0.2,
- 5) PSA-D  $>0,25$  is acceptable if MRI is negative or if targeted biopsies show no more than Gleason score 3+3 or 3+4 without invasive cribriform and intraductal carcinoma (CR/IDC) Patients with a PSA D  $\geq 0.25$  at inclusion can be followed outside the actual PRIAS protocol.
- 6) Clinical stage T1C or T2.
- 7) Gleason score 3+3=6 or Gleason score 3+4 without invasive CR/IDC.
- 8) Total number of positive cores allowed:
  - 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).
  - c. If more than 2 TRUS-guided biopsy cores are positive (Gleason score 3+3 or 3+4 without CR/IDC) an MRI is indicated. If the MRI is negative or if targeted biopsies show no more than Gleason score 3+3=6 or 3+4=7 without invasive CR/IDC, inclusion is possible.
  - d. For patients with Gleason score 3+4 without invasive CR/IDC, the maximum number of positive cores should be  $\leq 50\%$ , where multiple positive cores from the same lesion on MRI count for one positive core.
- 9) Participants must be willing to attend the follow-up visits.
- 10) Signed informed consent.

### Exclusion criteria:

- 1) Men who can not or do not want to be radiated or operated.
- 2) A former therapy for prostate cancer.
- 3) For patients with a life expectancy of  $<10$ yr, watchful waiting is preferred above Active Surveillance.

## Active Surveillance: Criteria for follow-up



### Time table

Year*	1					2				3		4		5		6		7	
Month	0	3	6	9	12	15	18	21	24	30	36	42	48	54	60	66	72	78	84
PSA-test	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
DRE	X		X		X		X		X		X		X		X		X		X
MRI + targeted biopsies		X**			X								X						X
Systematic Biopsy	X				X								X						X
Evaluation	X	X	X		X		X		X		X		X		X		X		X

\* Time of diagnosis

\*\* MRI after 3 months with targeted biopsies only if no MRI is used before diagnosis

Repeat biopsies after 1, 4, 7 and 10 years and subsequently every 5 years.