

Amendment 15

Date of amendment: 13 January, 2023

Protocol change: Men with PSA ≥ 1.2 are re-invited every 2 years with PSA testing up to stop age irrespective of previous study results if not being detected with PC (See amendment 14).

Compared to previous algorithm that included MRI in all men with PSA above the cut-off, MRI (and also systematic biopsies in arm 1) will now not be performed if there is an MRI within 5 years that was classified as PI-RADS 1-2 and the PSAD is below 0.1 and the total PSA < 10 ng/mL. The PSAD is calculated from the actual PSA divided with the most recent prostate volume obtained by MRI. This new algorithm is valid in all three study-arms. Men with PSA ≥ 10 ng/mL, men who for various reasons cannot undergo MRI and men with an inconclusive MRI follow previous algorithm (see amendment 12 and 13).