# Regional forskningsstøtte – forsker/studiegruppers perspektiv

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Urologisk Seksjon

Sykehuset i Vestfold

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*Urology*. 2011 May ; 77(5): 1025–1026. doi:10.1016/j.urology.2011.01.054.

# Great Meaningless Questions in Urology: Which Is Better, Open, Laparoscopic, or Robotic Radical Prostatectomy?

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# Hva gjør vi med eldre menn som har potensielt farlig prostatakreft?

# Late-Stage Prostate Cancer and Prostate Cancer Mortality

A Population-Based Study

Sven Löffeler

Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
2019

**Radikal Prostatektomi <70 år**

**Radikal strålebehandling <75 år**

# Bakgrunn for aldersgrensene

- Egentlig uklart, ikke nedfelt i retningslinjer
- Lite eller ingen level 1 evidens som støtter kurativt intendert behandling
- Konservativ behandling er tilstrekkelig behandling hos eldre menn
- Kort forventet levetid

# Kort forventet levetid?

(Source: Statistics Norway/ Denmark/ Finland/ Sweden)

| Age (years) | Average Life Expectancy (years) | | | |
|---|---|---|---|---|
| | **Norway** | Denmark | Finland | Sweden |
| At 75 | **12** | 11 | 11 | 12 |
| At 80 | **9** | 8 | 8 | 8 |
| At 82 | **8** | 7 | 7 | 7 |
| At 85 | **6** | 6 | 6 | 6 |

Original Article

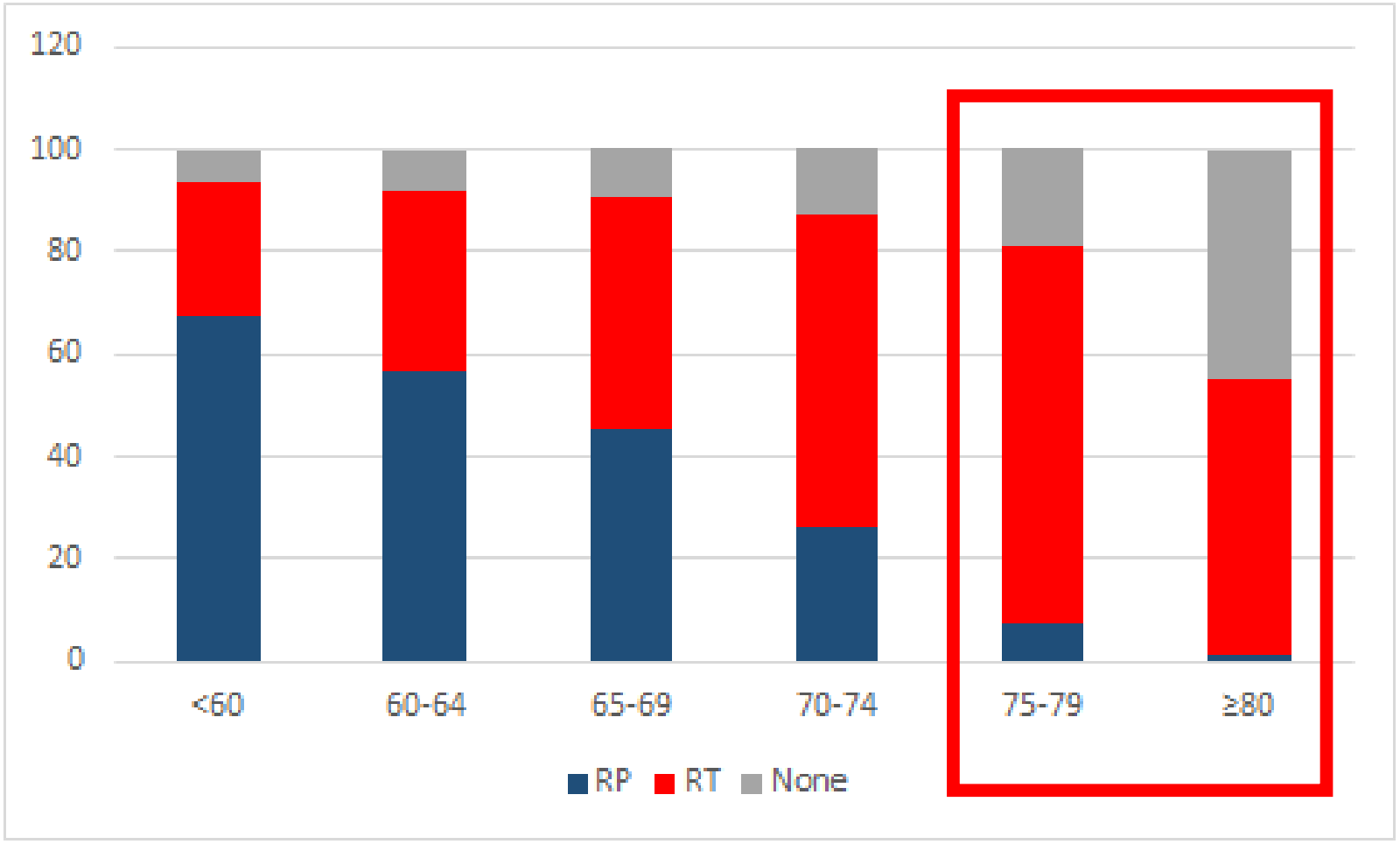
# Receipt of Definitive Therapy in Elderly Patients With Unfavorable-Risk Prostate Cancer

David D. Yang, BA [1]; Brandon A. Mahal, MD[2]; Vinayak Muralidhar, MD, MSc[2]; Ninjin Boldbaatar, MPH[3]; Shelby A. Labe, BS[3]; Michelle D. Nezolosky, BA[3]; Marie E. Vastola, BS[3]; Clair J. Beard, MD[1,3]; Neil E. Martin, MD, MPH[1,3]; Kent W. Mouw, MD, PhD[1,3]; Peter F. Orio III, DO, MS[1,3]; Martin T. King, MD, PhD[1,3]; and Paul L. Nguyen, MD[1,3]

Cancer December 15, 2017

National Cancer database (NCDB)
411 000 menn med PCa
- intermediær risiko: 248 000
- høy risiko: 163 000
- diagnose 2004-2012:

# **High risk** (N=163 146)




Gleason 8-10
cT2c-T4
PSA>20

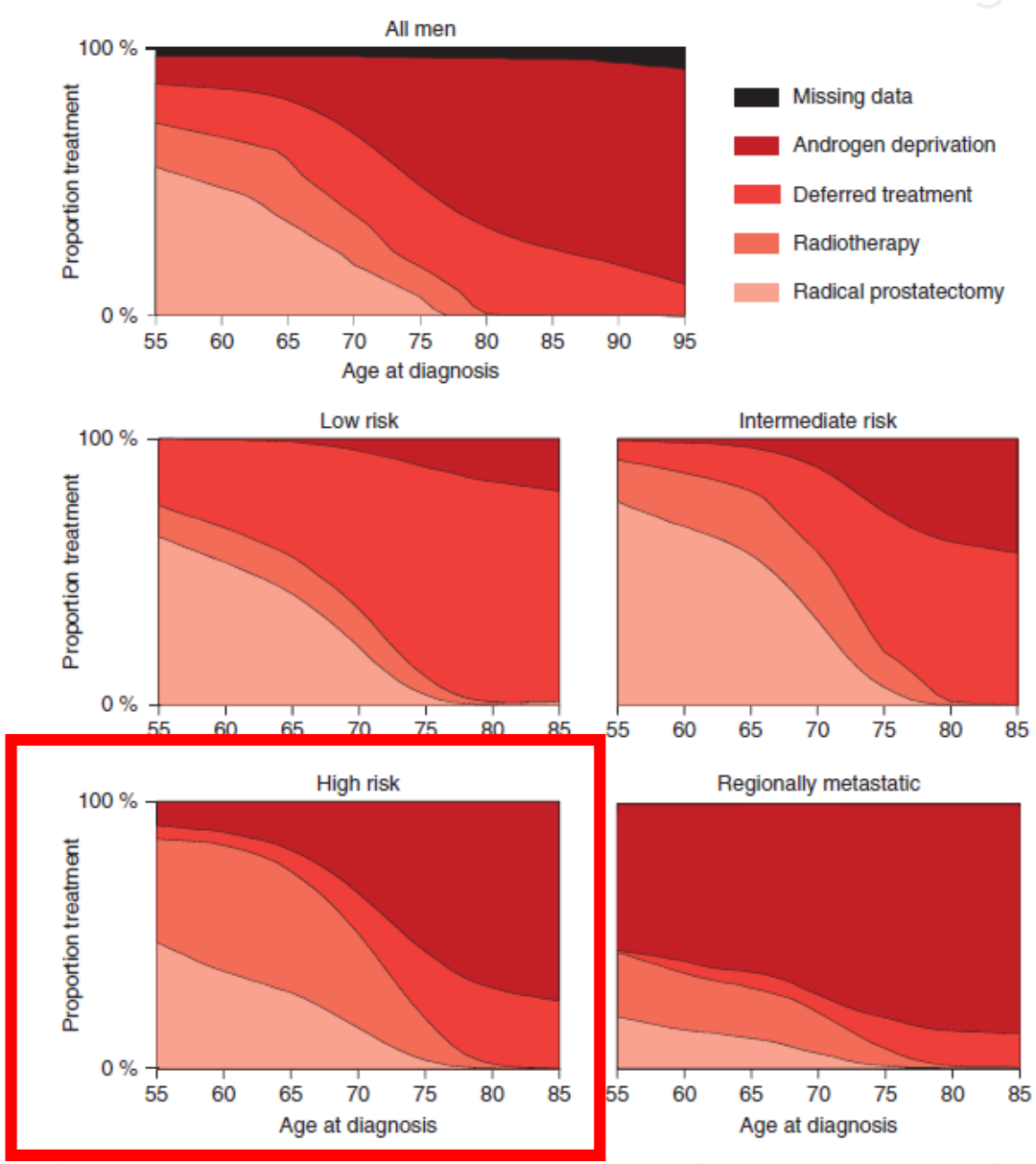
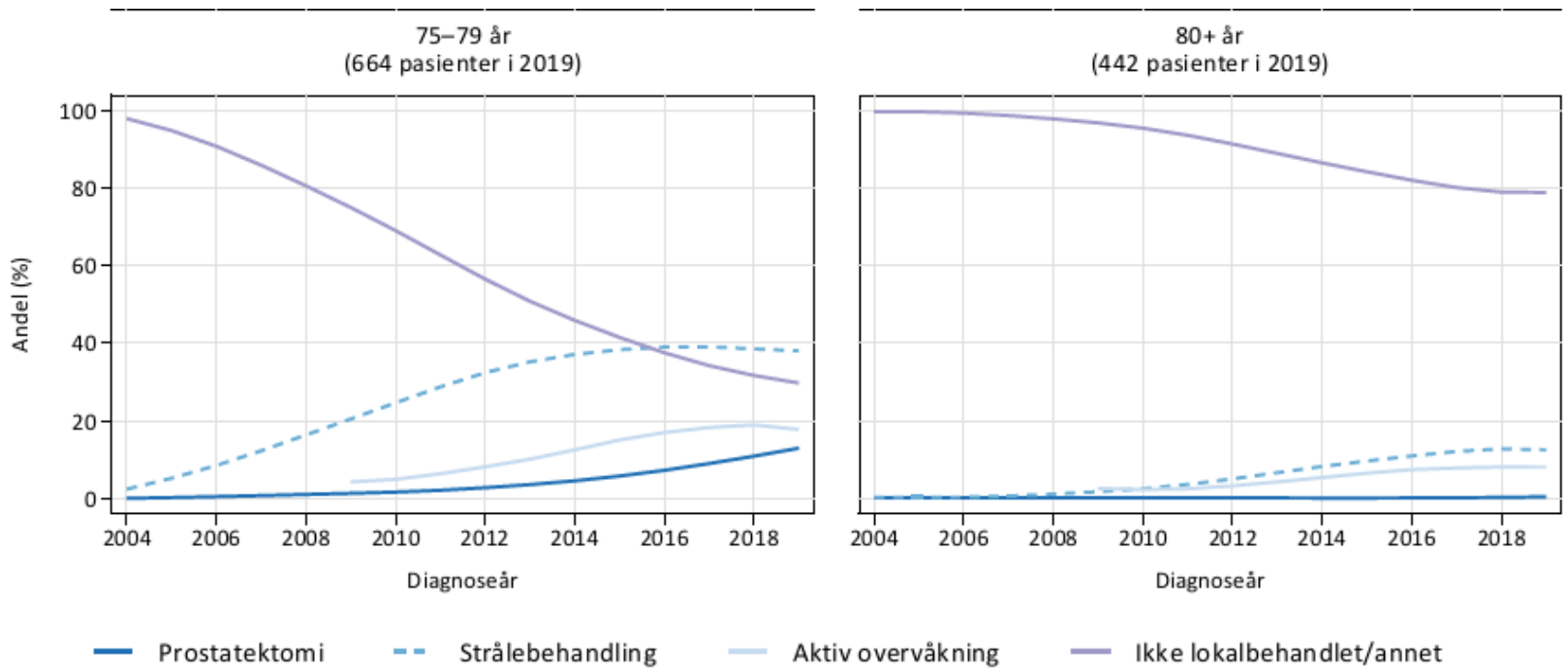



**Figure 1.** Proportion of men treated with radical prostatectomy, radiotherapy, deferred treatment (i.e. watchful waiting or active surveillance) or androgen deprivation therapy by age at diagnosis among 121 392 men in PCBaSe diagnosed with prostate cancer between 1998 and 2012. Proportions were calculated in 1-year classes and smoothed by locally weighted regression.

Pettersson et al.

*Annals of Oncology* 29: 377–385, 2018
doi:10.1093/annonc/mdx742
Published online 17 November 2017

# Årsrapport for prostatakreft 2020
# **Kreftregisteret**

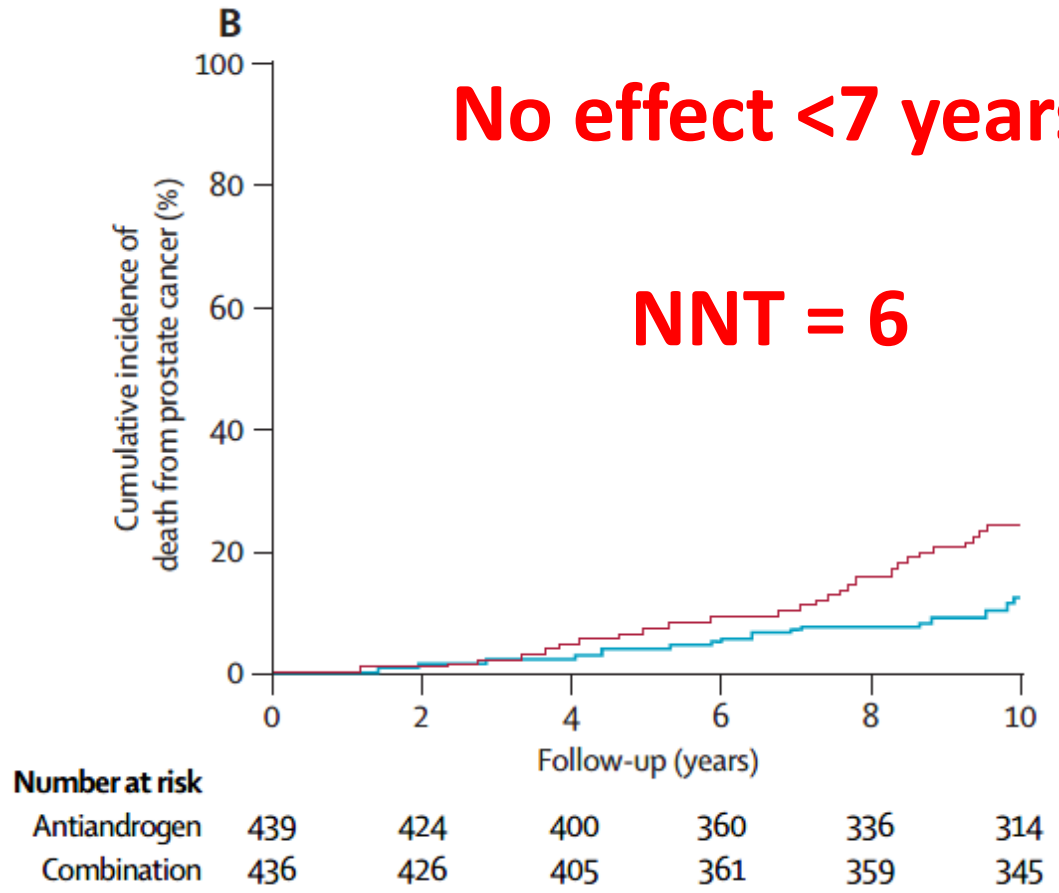



**Figur 11.4:** Behandlingsvalg fordelt på aldersgrupper (diagnoseår 2004–2019), nasjonalt

# SPCG 7: prostate-cancer-specific-mortality

- **At 7 years**:
  - 9.9% versus 6.3% (ikke signifikant)
  - Difference 3,6%

- **At 10 years**:
  - 23.9% versus 11.9%
  - >50% risk reduskjon




**No effect <7 years**

**NNT = 6**

# Så hva gjør vi med eldre menn som har potensielt farlig prostatakreft?

# Hva gjør man da som vanlig lege på et lokalsykehus?

# Kurs i forskerinitierte kliniske studier – fra idé til publikasjon

# Regional Forskningsstøtte

**Statistikk**
Maiju + Inge

**Admin + budsjett**
Martin + Marielle

**Koordinering**
Berit + Hege Cecilie

**Helseøkonomi**
Linn + Lars

**Database**
Mats + Cecilie

**Monitorering**
Jacob

A randomized, controlled, open-label,phase III prospective, multicenter intervention trial of immediate curative therapy versus conservative treatment in older patients with non-metastatic, high-risk prostate cancer

Get-RANDomized–Prostate (GRAND-P); SPCG 19

# Protokollgruppe







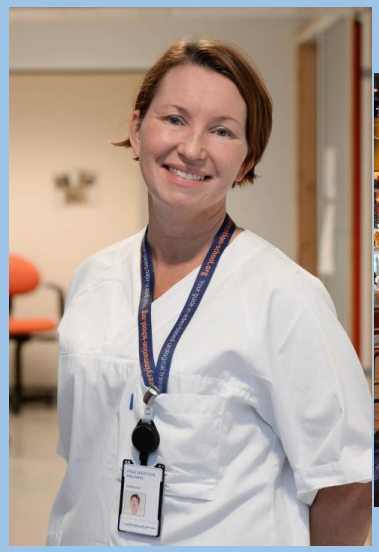





ANTON SPORT
787













# Formålet med studien

- Hovedformålet med studien er å evaluere om kurativt intendert behandling forlenger livet og/ eller forbedrer livskvaliteten hos eldre pasienter med ikke-metastatisk, høy-risiko prostatakreft

# Endepunkter

## Primærendepunkter

- Overall survival
- Burden of disease (ELD 14)

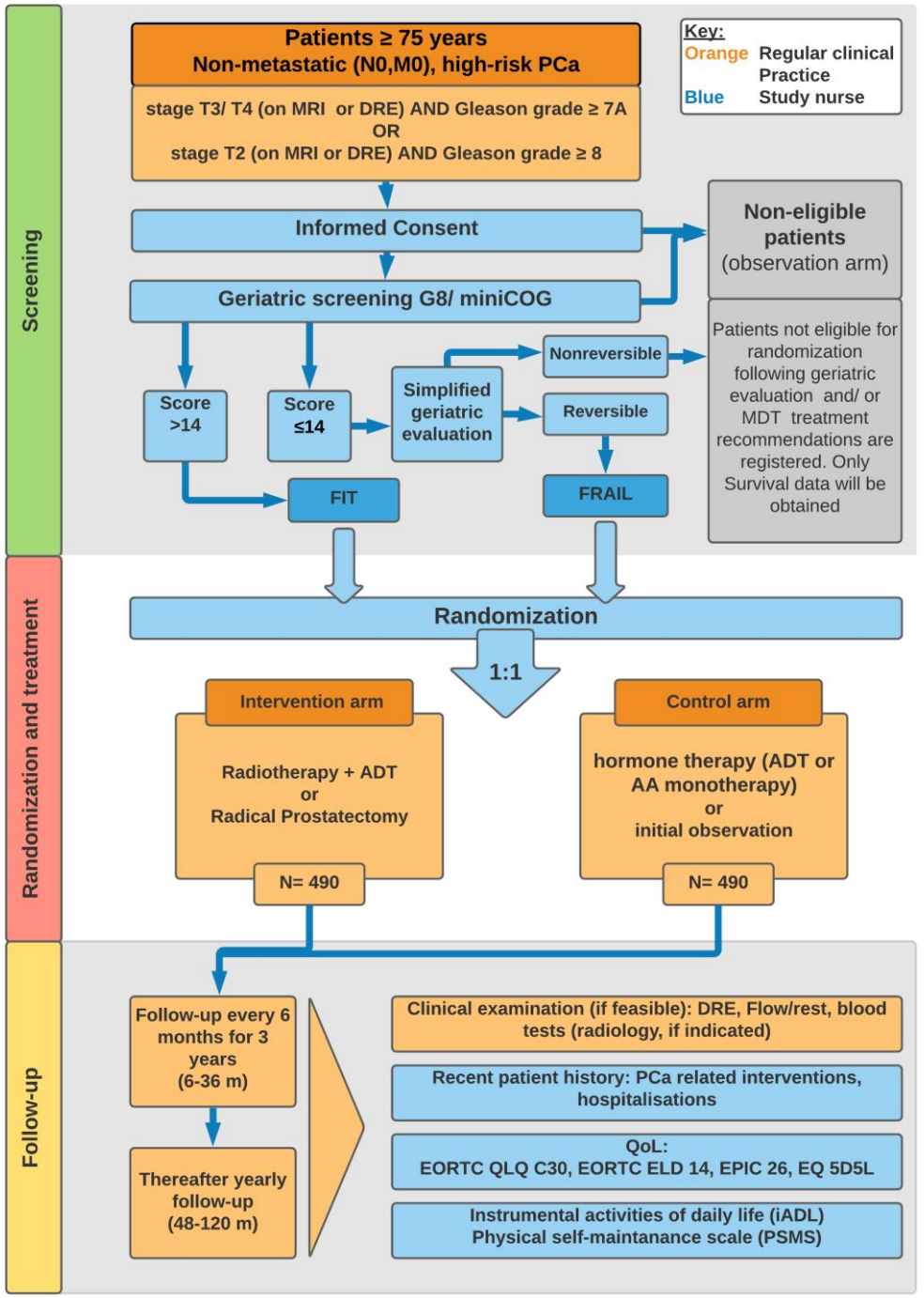
## Sekundære endepunkter

- Quality of Life scales:
    - Role functioning (RF2, EORTC QLQ-C30)
    - Urinary Irritative/ Obstructive and Bowel (EPIC-26 score)
- **Pca morbidity (hospitalizations, interventions, complications due to local progression, complications due to systemic progression)**
- Prostate-cancer specific survival
- Metastasis-free survival
- **Symptom/ intervention-free survival**
- Need for secondary and tertiary systemic therapies
- **Quality adjusted life years (EQ 5D 5L)**

# Eksplorative endepunkter

- Quality of life scales measured by EORTC QLQ-C30, EORTC ELD14, EPIC-26, EQ-5D-5L
- Lawton and Brody personal and instrumental activities of daily life (pADL/iADL)
- Intervention related treatment costs/ personnel costs during follow-up
- Health care costs/direct costs, mainly related to use of health care services, such as hospitalization, outpatient visits, medications, complications due to treatment, additional treatment.
- Need for institutionalized care

# Study Flowchart

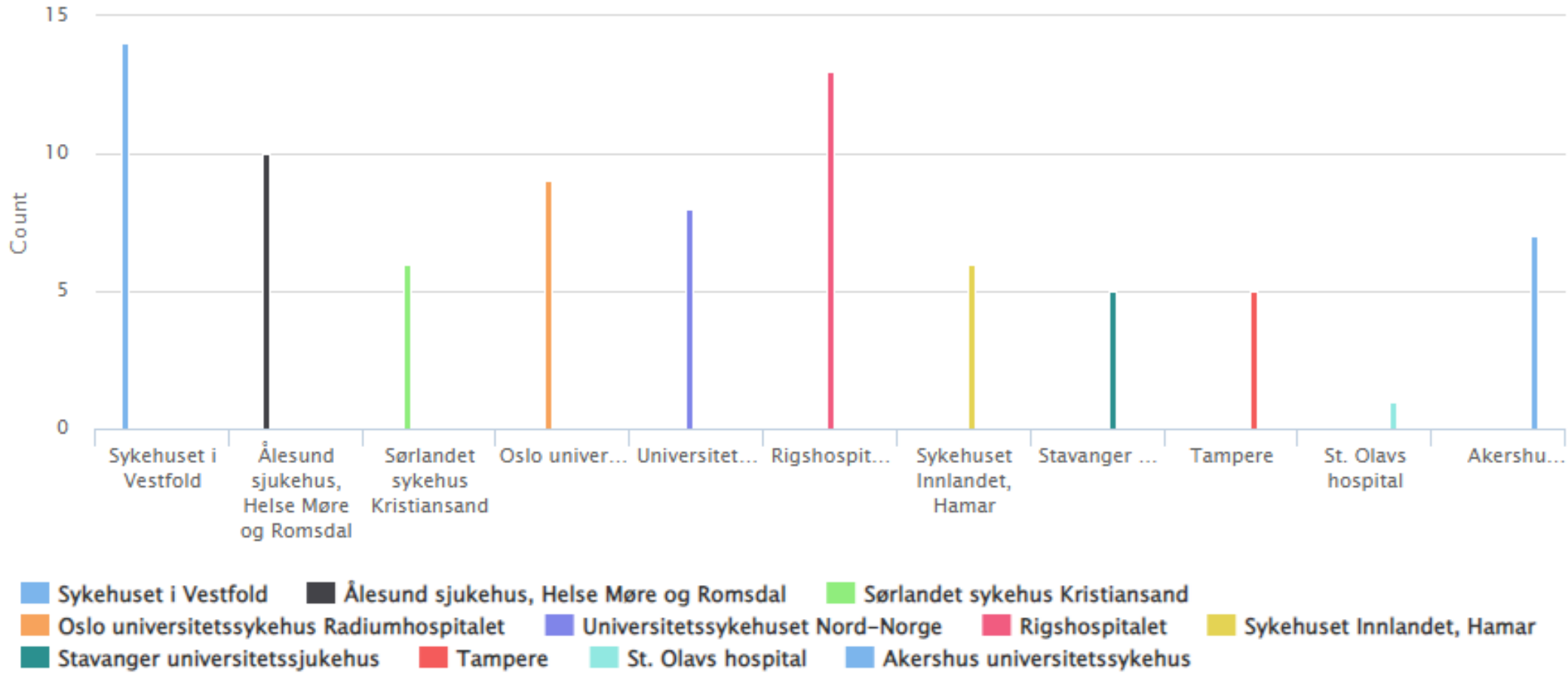


# Finansiering

- **KlinBeforsk (19,3 millioner NOK)**
- **Kreftforening (6,9 millioner NOK)**
- **Helse Sør Øst (post doc stilling)**
- **Nordic Cancer Union (75 000 Euro)**
- **Privat donor (1 million NOK)**
- **Prostatacancerförbundet (820 000 SEK)**

# Status

**13 aktive sentre i Norge, Danmark og Finland**


15
10
5
0
Count
Sykehuset i Vestfold
Ålesund sjukehus, Helse Møre og Romsdal
Sørlandet sykehus Kristiansand
Oslo univer...
Universitet...
Rigshospit...
Sykehuset Innlandet, Hamar
Stavanger ...
Tampere
St. Olavs hospital
Akershu...
Sykehuset i Vestfold
Ålesund sjukehus, Helse Møre og Romsdal
Sørlandet sykehus Kristiansand
Oslo universitetssykehus Radiumhospitalet
Universitetssykehuset Nord-Norge
Rigshospitalet
Sykehuset Innlandet, Hamar
Stavanger universitetssjukehus
Tampere
St. Olavs hospital
Akershus universitetssykehus

# Status

- **78 randomiserte pasienter**
- **(66 pasienter i observasjonsgruppen)**

# Status

- 11 aktive sentre i Norge: Tønsberg, Ålesund, Oslo, Hamar, Kristiansand, Tromsø, Stavanger, Trondheim, AHUS, Drammen, Skien
- Danmark: Rigshospitalet, Copenhagen (+ 4 sentre til snart)
- Finland: Tampere (3 sentre til)
- Sverige: etisk godkjenning oktober 2023, oppstart 2024
- UK? Italia?

# Takk for oppmerksomheten!