

Norrköping Randomised Controlled Trial of Prostate Cancer Screening

Submission date 26/04/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 15/06/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/05/2011	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
92044 (Linköping, Sweden, 1987)

Study information

Scientific Title
Prostate screening for men aged 50-69 in Norrköping, Sweden: A twelve-year randomised controlled trial with twenty-year follow up

Study objectives

Screening for prostate cancer is cost effective, well accepted and reduces prostate cancer mortality

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee, Faculty of Health Sciences in Linköping (forskningsetikommittén, Hälsouniversitetet i Linköping) approved on the 8th of April 1992 (ref: 92044)

Primary study design

Interventional

Study design

Randomised Controlled Trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Prostate Cancer

Interventions

1494 men were randomly selected from a population of 9026 men aged 50-69 (the total male population of that age in the area).

Information was issued through local media and an invitation to screening sent to selected individuals.

Screening was conducted every third year from 1987-1996. Digital rectal examination only was performed in 1987 and 1990. PSA testing (cut-off level 4 ng/ml) was added in 1993 and 1996.

The total duration of follow up was 15-20 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Prostate Cancer mortality, determined by obtaining data from the Swedish Central Death Register on date and cause of death. Cause of death was also checked in the South-East Region Prostate Cancer Register.

Key secondary outcome(s)

1. Cost effectiveness, determined when twelve year survival data were accessible
2. Acceptance, assessed by questionnaires immediately after the screening examinations
3. Diagnostic accuracy

Further information on the outcomes and methods of assessment may be found in the publications below.

Completion date

31/12/2010

Eligibility

Key inclusion criteria

Men aged 50-69 years in 1987 residing in Norrköping, Sweden.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/1987

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Sweden

Study participating centre

Department of Urology

Linköping

Sweden

581 91

Sponsor information

Organisation

Research Council of Southeast Sweden (Forskningsrådet i Sydöstra Sverige) (Sweden)

ROR

<https://ror.org/0326gsy75>

Funder(s)

Funder type

Research council

Funder Name

The Research Council in the SouthEast Region of Sweden (Sweden) - (number F97-318)

Funder Name

The Swedish Cancer Foundation (Sweden)

Funder Name

County Council of Östergötland (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/04/1990		Yes	No
Results article	results on cost effectiveness	01/12/1990		Yes	No
Results article	results	01/12/1992		Yes	No
Results article	results	01/08/1993		Yes	No
Results article	results	01/12/2004		Yes	No
Results article	20 year follow up results	31/03/2011		Yes	No