# External radiotherapy versus expectancy in localized prostate cancer

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
08/08/2011		☐ Protocol		
Registration date 26/09/2011	Overall study status Completed Condition category Cancer	Statistical analysis plan		
		Results		
Last Edited		Individual participant data		
19/05/2017		<ul><li>Record updated in last year</li></ul>		

### Plain English summary of protocol

Background and study aims

Prostate cancer is a common cancer, where many patients have such a slowly growing tumor that it is uncertain if they need treatment. Other patients have very aggressive tumors, and in Sweden with 10000 newly diagnosed prostate cancer patients 2500 will die each year. No scientific studies had in 1986 shown that any of the treatment options for localized prostate cancer expectancy or radiotherapy or surgery was superior. Expectancy had been the treatment of choice in the beginnings of the 1980s. The aim of this study was to evaluate if radiotherapy could prolong progression free survival and reduce mortality in comparison to expectancy.

Who can participate?

Patients with prostate cancer under the age of 75

What does the study involve?

Participants are followed for the progression of their symptoms and are offered radiotherapy. The use of four-field EBRT, 64 Gy, 2.0 cm margin was increased during the beginning of 1980's, further technical improvements such as CT-based conformal radiotherapy was developed by the beginning of the 1990ies, dose was increased to 70 Gy with margins around 1-1.5 cm.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Umeå University (Sweden)

When is study starting and how long is it expected to run for? April 1986 to January 1997

Who is funding the study?

- 1. Cancer Research Foundation (Sweden)
- 2. Lions Cancer Research Foundation, Umea University (Sweden)
- 3. Umeå University Hospital (Sweden)

Who is the main contact?
Professor Andrew Widmark
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## Contact information

## Type(s)

Scientific

#### Contact name

**Prof Anders Widmark** 

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## Additional identifiers

#### Protocol serial number

Version 1991 and 1995 04

## Study information

#### Scientific Title

External radiotherapy versus expectancy in low-intermediate risk localized prostate cancer: a randomized trial

## Study objectives

To investigate if radiotherapy will prolong progression free survival and reduce mortality in prostate cancer in early localized prostate cancer in comparison to active expectancy.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Study was part of the regular treatment program for localized prostate cancer in Northern Sweden (Ethics approval not necessary at that time [1996]).

## Study design

Randomized open multi-center trial

## Primary study design

Interventional

#### Study type(s)

**Treatment** 

#### Health condition(s) or problem(s) studied

Prostate cancer

#### **Interventions**

Expectancy: Patients included: 107 out of (130) 160, Patients followed until symptomatic clinical progression, and then offered radiotherapy

Radiotherapy: Patients included: 107 out of (130) 160, Treated with 64-70 Gy, boxfield or conformal radiotherapy, and than follow up, until clinical progression and than castration treatment

#### Intervention Type

Other

#### Phase

Phase III

#### Primary outcome(s)

- 1. Progression Free survival
- 2. Overall survival

## Key secondary outcome(s))

Morbidity

#### Completion date

27/01/1997

# **Eligibility**

#### Key inclusion criteria

- 1. Patients with verified localized prostate cancer, T1-T2b, pN0, Grade 1 and 2, M0
- 2. Age less than or equal to 75 years
- 3. Surgical obturatorious lymph node staging, with no signs of positive lymph nodes
- 4. No signs on metastasis after clinical investigation, bone scan and pulmonary X-ray
- 5. No previous treatment against their prostate cancer
- 6. No other known malign or benign disease that would shorten their lifes in relation to a healthy population
- 7. Patients approval of participation

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Male

## Key exclusion criteria

Patients not willing to participate in the long follow up program

#### Date of first enrolment

23/04/1986

#### Date of final enrolment

27/01/1997

## Locations

#### Countries of recruitment

Denmark

Norway

Sweden

## Study participating centre Umeå University

Umeå Sweden

SE - 90187

# Sponsor information

## Organisation

Umeå University Hospital (Sweden)

#### **ROR**

https://ror.org/012k96e85

# Funder(s)

## Funder type

Government

#### **Funder Name**

Cancer Research Foundation (Sweden)

## Alternative Name(s)

The Cancer Research Foundation, CRF

## **Funding Body Type**

Government organisation

## **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

United States of America

#### **Funder Name**

Lions Cancer Research Foundation, Umeå University (Sweden)

#### Funder Name

Umeå university Hospital, Umeå (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?
Other publications		15/12/2001		Yes	No
Other publications		01/12/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes