

External radiotherapy versus expectancy in localized prostate cancer

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

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, Umeå 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
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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]).

Primary study design
Interventional

Study design
Randomized open multi-center trial

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 then follow up, until clinical progression and then 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