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Phase III study of HYPOfractionated RadioTherapy of intermediate risk localised Prostate Cancer

Submission date 09/12/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/02/2009	**Overall study status** Completed	
Last Edited 15/01/2021	**Condition category** Cancer	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Anders Widmark

Contact details
Department of Oncology
Umeå University Hospital
Umeå
Sweden
SE-901 85

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Hypofractionated radiotherapy of intermediate risk localised prostate cancer: a phase III, randomised, open, multicentre trial

Acronym
HYPO-RT-PC

Study hypothesis
To demonstrate a 10% unit increase (70% to 80%) in freedom from failure (prostate specific antigen [PSA] or any clinical test) in the HYPO-RT arm at 5 years after the end of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Regionala etikprövningsnämnden i Umeå) gave approval on the 9th December 2003 (ref: 03-513)

Study design
Phase III randomised open multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at http://www.oc.umu.se/ (Swedish only) under PDF-dokument/Kliniska studier: HYPO-RT-PC

Condition
Intermediate risk localised prostate cancer

Interventions
Treatment technique:
The radiation treatment shall be given with external photon beam therapy with three-dimensional conformal radiotherapy (3D-CRT) and/or intensity modulated radiation therapy (IMRT) techniques. It is left to each centre to decide upon the optimal technique (number of beams, beam weights, beam angles, beam shaping, etc). The same treatment technique shall be used in both trial arms within the centre. The position of the prostate shall be verified prior to every fraction with electronic kV or MV portal imaging or x-ray volumetric imaging (cone beam

CT) using implanted markers. The treatment should start as soon as readily possible after the verification/correction. The monitor units (dose) used for verification of position should be considered and compensated for if MV portal imaging is used. Each centre should have treated at least two patients with their specific marker and image guidance technique before entering the study.

Fractionation schedule and treatment durations:
Conventional arm: radiotherapy is given daily (5 days/week) with 39 fractions of 2.0 Gy, i.e. total 78.0 Gy. The total treatment time is 53 - 55 days. Maximum allowed treatment days are 65.
Hypofractionated arm: radiotherapy is given working-days with 7 fractions of 6.1 Gy, i.e. total 42.7 Gy. The total treatment time is 15 - 19 days. Treatment is given every other weekday, always including two weekends.

Clinical follow up:
Patients should be seen by a doctor (urologist/surgeon or oncologist) for clinical evaluation every 3 months (+ 14 days) preferentially by an oncologist for the first year, and every six months (+ 28 days) thereafter until metastases are verified. Thereafter patients should be followed for verification of death.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Freedom from failure (PSA or any clinical), measured five years after the end of treatment.

Secondary outcome measures
1. PSA response rate
2. Time to symptoms related to local progression
3. Time to symptoms related to distant progression
4. Cancer specific survival
5. Overall survival
6. Quality of Life (QoL) and side effects with special focus on sexual function, urinary and gastrointestinal morbidity

Measured five years after the end of treatment.

Overall study start date
01/07/2005

Overall study end date
30/06/2015

Eligibility

Participant inclusion criteria
1. Men less than 75 years of age and, as judged by the doctor, a life expectancy of 10 years (except for cancer) at time of randomisation with performance status World Health Organization (WHO) grades 0 - 2

2. Patients with a histologically verified prostatic cancer
3. Patients with intermediate risk prostatic cancer of clinical category T1c - T3a with one or two of the following risk factors:
3.1. T3a or Gleason greater than 7
3.2. PSA greater than 10 according to the TNM classification system UICC 2002
4. PSA less than 20 µg/L
5. The patients should have no evidence of metastases according to the definition above
6. Patients should be lymph node negative according to the definition above, i.e. staging
7. Patients should be suitable for radiotherapy
8. Patients must have signed informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
In total: 592

Total final enrolment
1200

Participant exclusion criteria
1. Patients who earlier have undergone any other treatment for prostatic cancer
2. Patients unable to co-operate or suffering from any other form of disease that would interfere with the planned treatment (e.g. colitis)
3. Patients with previous diagnosis of other malignant disease. Exceptions could be made for basal cell carcinoma of the skin or progression free survival at least 10 years after any previous tumour.
4. Previous hormone therapy (castration or anti-androgens)
5. Any condition that prevent markers implantation, i.e. anal fissure

Recruitment start date
01/07/2005

Recruitment end date
30/06/2015

Locations

Countries of recruitment
Sweden

Study participating centre

Department of Oncology
Umeå
Sweden
SE-901 85

Sponsor information

Organisation
County Council of Västerbotten (Västerbottens läns landsting [VLL]) (Sweden)

Sponsor details
-
Umeå
Sweden
901 89
-
landstinget@vll.se

Sponsor type
Hospital/treatment centre

Website
http://www.vll.se

ROR
https://ror.org/04xvhsp09

Funder(s)

Funder type
Research organisation

Funder Name
Nordic Cancer Union (Nordiska Cancerunionens [NCU]) (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	03/08/2019	24/06/2019	Yes	No
Results article	quality of life results	01/02/2021	15/01/2021	Yes	No