ISRCTN78176828 https://doi.org/10.1186/ISRCTN78176828

Radiotherapy with scanning beam protons for locally advanced prostate cancer or localised prostate cancer with risk factors

Submission date 10/08/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/10/2009	**Overall study status** Completed	
Last Edited 24/07/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Martin Stuschke

Contact details
Klinik und Poliklinik für Strahlentherapie
Medizinische Fakultät
Universität Duisburg-Essen
Hufelandstrasse 55
Essen
Germany
45122

Additional identifiers

Protocol serial number
WPE 08-12

Study information

Scientific Title

Radiotherapy with scanning beam protons for locally advanced prostate cancer or localised prostate cancer with risk factors: a phase II non-randomised prospective study

Acronym
ProPro

Study objectives
Intensity modulated proton radiotherapy using small size pencil scanning beam is able to deliver highly conformal dose distributions to large target volumes with low integral doses to surrounding tissues. It is the aim of this study to characterise toxicity and effectiveness of this method given at total doses in the upper standard range and with conventional fractionation to target volumes including the prostate, the seminal vesicles, and if the patient denies laparoscopic lymph node sampling, to the pelvic lymph nodes at risk.

As of 12/10/2009, this record has been updated to include extended anticipated start and end dates to this trial due to a delayed start of the clinical treatments at the proton facility. The initial anticipated start and end dates of this trial were as follows:
Initial anticipated start date: 01/10/2009
initial anticipated end date: 01/10/2014

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Ethik-Kommision of Universitätsklinikum Essen) approved on the 12th May 2009 and the 1st July 2009 (ref: 09-4006)

Study design
Non-randomised prospective phase II study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
The patients are separated in different treatment groups according to their pre-registration staging. According to these groups the planning target volumes (PTVs) 1 - 3 will be contoured and treated. There are two ways of proton therapy. Patients who accepted staging lymphadenectomy will receive local treatment of prostate (see treatment group A) and those who refused staging lymphadenectomy will receive loco-regional radiotherapy of the prostate and regional lymph nodes (see treatment group B).

Treatment Group A:
Registered patients, who received a staging lymphadenectomy, are treated in treatment group A.

Prostate: 78 Gy 1.1/39 fractions
Seminal vesicles: 60 Gy 1.1/30 fractions
ADT performed

Treatment Group B:
All patients registered who did not accept the recommended staging lymphadenectomy and who do not refuse androgen deprivation therapy are treated in treatment group B.
Prostate: 78 Gy 1.1/39 fractions
Seminal vesicles: 60 Gy 1.1/30fractions
Regional nodes: 50 Gy 1.1/25 fractions
ADT performed

Treatment Group C:
Patients registered who refuse androgen deprivation or who did not have staging laparoscopy and refuse pelvic node irradiation will be irradiated according to treatment group A. Androgen deprivation is strongly recommended but not mandatory to be treated.

Contact details for patient information sheet:
Dr Dirk Geismar
Westdeutsches Protonentherapiezentrum Essen (WPE)
Hufelandstr. 55
45147 Essen
Germany
Email: dirk.geismar@uk-essen.de

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Incidence of severe late GU and GI toxicity defined as grade 3 - 5 GU and GI complications according to Common Terminology Criteria for Adverse Events version 3.0 (CTCAE v3.0) appearing or persisting greater than 120 days after treatment start at 24 months after treatment start (late treatment-related adverse events).

Key secondary outcome(s))
1. Rate of biochemical failure
2. Overall survival
3. Disease specific survival
4. Rate of clinical progressions and time to clinical progression - local/regional and distant relapse
5. Acute toxicity (GU/GI) greater than or equal to grade 3 (CTC 3.0)
6. Rate of acute grade 2 toxicity (GU/GI) (CTC 3.0)
7. Rate of late grade greater than or equal to 2 GU and GI toxicity

Measured 24 months after treatment start. Acute toxicity is measured until 120 days after treatment start. A follow-up of 2 years after treatment start is required, however, a long term follow-up is recommended. Thus, rate of biochemical failure, overall survival, disease specific survival and rate of late toxicity will possibly be evaluated after 5 years and longer.

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Histologically confirmed prostate cancer with one of the following combinations:
1.1. T3-T4 or Gleason greater than or equal to 8 or prostate specific antigen (PSA) greater than 20 and less than 50 ng/ml
1.2. T1c-T2a and Gleason 7 and PSA greater than 10 and less than or equal to 20 ng/ml
1.3. T2b-T2c and Gleason 7 or PSA greater than 10 and less than or equal to 20 ng/ml
2. Performance status World Health Organization (WHO) less than or equal to 2
3. No evidence of distant metastases. Minimum work-up: a negative bone scan and an actual PSA-value within 2 months prior to registration are required.
4. Negative regional lymph nodes as established by staging lymphadenectomy. For patients denying staging lymphadenectomy, an actual computed tomography (CT) or magnetic resonance imaging (MRI) scan has to be negative for lymph node metastases.
5. Men of child-producing potential must be willing to consent to use effective contraception
6. Aged greater than or equal to 18 years
7. Patients must give study specific informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. PSA greater than or equal to 50 ng/ml
2. Evidence of distant metastases
3. Pathological proven positive lymph nodes or regional lymph nodes greater than 1.0 cm in the smallest diameter on imaging studies
4. Prior radical prostatectomy or cryosurgery for prostate cancer
5. History of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
6. Prior pelvic radiotherapy or brachytherapy
7. Prior systemic chemotherapy for the study cancer
8. Current or continuing anti-coagulation with Coumadin or equivalent
9. Transurethral resection of the prostate or urethrotomia less than 6 months before radiotherapy
10. Prior radical prostatectomy, cryosurgery for prostate cancer, or bilateral orchiectomy for any cancer

11. Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 3 years
12. Severe, active co-morbidity, defined as follows:
12.1. Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration
12.2. Acquired immune deficiency syndrome (AIDS) based upon current Centers for Disease Control and Prevention (CDC) definition; note, however, that human immunodeficiency virus (HIV) testing is not required for entry into this protocol
12.3. Hip implants
12.4. Major medical or psychiatric condition which in the investigators opinion will prevent completion of the treatment and interfere with follow-up
12.5. Pre-existing of those gastrointestinal (GI) or genitourinary (GU) symptoms of Grade greater than 1 on the Common Toxicity Criteria (CTC) late effect scale, that are considered for the primary end point

Date of first enrolment
01/04/2010

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Germany

Study participating centre
Klinik und Poliklinik für Strahlentherapie
Essen
Germany
45122

Sponsor information

Organisation
University Hospital Essen (Universitatsklinikum Essen) (Germany)

ROR
https://ror.org/02na8dn90

Funder(s)

Funder type

Research organisation

Funder Name
West German Proton Therapy Centre Essen (Westdeutsches Protonentherapiezentrum Essen [WPE]) gGmbH (Germany)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes