

Single Blind Randomized Phase III Trial to Investigate the Benefit of a Focal Lesion Ablative Microboost in Prostate Cancer

Published: 12-05-2009

Last updated: 06-05-2024

- Primary study objective: To demonstrate the superiority of the ablative microboost dose schedule regarding 5-year biochemical no evidence of disease rate compared to the current standard of care.- Secondary study objectives: Establish and compare...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON44824

Source

ToetsingOnline

Brief title

FLAME trial

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Genitourinary tract disorders NEC

Synonym

prostate cancer

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ablative, Boost, Prostate, Radiotherapy

Outcome measures

Primary outcome

To decrease the five-year biochemical relapse rate with at least 10%.

Secondary outcome

Does the addition of an ablative microboost to the macroscopic tumour within the prostate change treatment related toxicity, quality of life or disease free survival.

Study description

Background summary

Dose escalation in external-beam irradiation has proven to benefit outcome in local prostate cancer. Randomized trials were performed up to doses of 78 Gy in 2 Gy fractions. Nevertheless, the five-year biochemical relapse rate still was approximately 35% in the high-dose arm. Therefore further dose escalation seems to be required. A feasibility study up to appr. 85 Gy on the entire prostate has already been performed and showed acceptable toxicity when combined with adequate position verification. Higher doses to the entire prostate are expected to increase severe toxicity. As local recurrences only occur at the site of the primary macroscopic tumour area the next step in increasing the dose should be an ablative boost to the macroscopic tumour alone, while electively irradiating the rest of the prostate to the current gold standard dose. Feasibility of this approach has been shown for an ablative dose of 95 Gy to the macroscopic tumour within the prostate.

Study objective

- Primary study objective: To demonstrate the superiority of the ablative microboost dose schedule regarding 5-year biochemical no evidence of disease rate compared to the current standard of care.
- Secondary study objectives: Establish and compare the rates of treatment-related toxicity, quality of life and disease-free survival.

Study design

Single blind prospective randomized controlled phase III trial.

Intervention

The standard arm receives the current gold standard, namely 77Gy to the prostate in 35 fractions of 2.2 Gy, 5 times per week. In the experimental arm patients receive in addition to the current gold standard of 77 Gy to the prostate an integrated boost to the macroscopically visible tumour to reach a total dose of 95 Gy in 35 fractions of 2.7 Gy, 5 times per week.

Study burden and risks

Patients will have to fill in a quality of life questionnaire before and after the radiotherapy treatments.

The risk associated with the increased dose to the macroscopic tumour is an increase of toxicity and a reduction of quality of life.

Contacts

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with intermediate or high risk local prostate cancer

WHO 0-2

Exclusion criteria

Low risk prostate cancer

WHO score >2

If an MRI cannot be performed

IPSS score >20

Previous pelvic irradiation

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	21-09-2009
Enrollment:	506

Type: Actual

Ethics review

Approved WMO	
Date:	12-05-2009
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	04-06-2010
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	07-03-2012
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	14-06-2017
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01168479

Register

CCMO

ID

NL26038.041.08