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

Published: 12-05-2009
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- 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...

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|---|---|
| **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

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## 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

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|---|---|
| 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 | ID |
| --- | --- |
| CCMO | NL26038.041.08 |