# Two-fraction Ultra-hypofractionated Radiotherapy with Focal Boost for low- and intermediate risk, localized prostate cancer (TURBO):phase II, randomized controlled clinical trial

Published: 18-01-2024
Last updated: 02-12-2024

To assess non-inferiority of treating patients with localized, intermediate risk prostate cancer in two fractions of 12 Gray (Gy) with a boost to the gross tumor volume of 13.5 Gy per fraction in 8 days, as compared to standard care (36.25 Gy in...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Miscellaneous and site unspecified neoplasms benign |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56580

**Source**
ToetsingOnline

**Brief title**
TURBO

### Condition

- Miscellaneous and site unspecified neoplasms benign
- Genitourinary tract disorders NEC
- Prostatic disorders (excl infections and inflammations)

**Synonym**
prostate adenocarcinoma, 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:** Localized prostate cancer, MR-guided radiation therapy (MRgRT), Patient reported outcomes (PROs), Ultrahypofractionation

## Outcome measures

### Primary outcome

difference in proportion of participants with acute (within 12 weeks after

start radiotherapy) CTCAE grade 2 or higher genitourinary toxicity

### Secondary outcome

• To assess physician reported toxicity (CTCAE) other than acute GU toxicity

• To assess patient reported outcome measures (PROMs), using the following

validated instruments:

o EORTC-QLQ-C30 (general quality of life for patients who undergo/underwent

oncological treatment)

o EQ-5D (cost-effectiveness and general QoL)

o EORTC-QLQ-PR25 (prostate-related quality of life after oncological therapy)

• To assess biochemical progression free survival and time to relapse, through

evaluation of PSA control and kinetics.

# Study description

### Background summary

Hypofractionation in prostate cancer radiotherapy has already led to a drastic reduction in fractionation scheme from 35 fractions to the now standard 5 fractions for patients with intermediate risk prostate cancer. Currently, biochemical progression free survival is at approximately 90% at five-year follow-up for intermediate risk prostate cancer patients, which leaves little to no room for further improvement in oncological outcomes. However, with an ageing population and a subsequently higher volume of patients with localized prostate cancer, there is a need to improve and optimize current treatment options. Treatment cost within the field of prostate oncology will further increase over the years to come, and an early economic health evaluation has demonstrated that a 2-fractionation scheme with MRI-guided radiotherapy (MRgRT) for intermediate risk prostate cancer patients can be cost effective compared to the standard of care 5 fractions scheme if adverse effects due to the treatment and operational costs are reduced..
Previous research demonstrated the feasibility of delivering high doses of radiation in only two fractions, both in silico as well as in a clinical setting using a conventional CT-guided linear accelerator. With the introduction of MRgRT, however, it has become possible to deliver higher doses of radiation with more accuracy, while limiting genitourinary (GU) and gastrointestinal (GI) toxicity. This leads us to believe that improvements can be made both in terms of costs as well as patient reported quality of life

## Study objective

To assess non-inferiority of treating patients with localized, intermediate risk prostate cancer in two fractions of 12 Gray (Gy) with a boost to the gross tumor volume of 13.5 Gy per fraction in 8 days, as compared to standard care (36.25 Gy in five fractions in 16-18 days), on an ELEKTA Unity MR-Linac system.

## Study design

single center, open label, phase II randomized clinical trial

## Intervention

Radiotherapy on the MR-Linac system, two fractions of 12 Gy with a boost on the tumor of 13.5 Gy each time, delivered in eight days.

## Study burden and risks

Participants will receive QOL questionnaires which are already embedded within the MOMENTUM-study. Therefore, participants are not subjected to an additional burden during the course and follow-up period of this study.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

• Age >=18 years
• Histopathological confirmation of prostate adenocarcinoma requiring radical treatment
• Intraprostatic tumor visible and delineable on diagnostic imaging
• EAU intermediate risk prostate cancer
o PSA < 20 ng/ml
o Gleason score <= 7
o cT1c-cT2b/iT3a (non-bulky, < 20mm)
• Written informed consent
• Informed consent to share medical data and fill out quality of life questionnaires in the MOMENTUM study.

### Exclusion criteria

• Contraindication to MRI (e.g., pacemaker)
• IPSS 15 or higher
• Prostate volume > 80 cc
• Comorbidities which predispose to significant toxicity (e.g., inflammatory bowel disease)
• Metal pelvic implants which cause artefact on MR-imaging sequences (e.g., total hip replacement)
• Previous radical prostatectomy
• Previous pelvic radiotherapy
• Previous invasive malignancy within the last 5 years, excluding basal cell carcinoma of the skin

## Study design

### Design

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| Study phase: | 2 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 28-03-2024 |
| Enrollment: | 160 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 18-01-2024 |
| Application type: | First submission |
| 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 |
|---|---|
| CCMO | NL85364.041.23 |