# The MR-Linac Technical Feasibility Protocol For Development of MR-guided Adaptive Radiation Therapy.

Published: 24-08-2018
Last updated: 12-04-2024

Primary: To test the feasibility of multiple techniques / software for MR-guided adaptive radiation therapy on the Elekta Unity MRL.Secondary: To register acute grade >= 3 toxicity.

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

## Summary

### ID

NL-OMON54848

**Source**
ToetsingOnline

**Brief title**
UMBRELLA-2

### Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

**Synonym**
Cancer, malignancy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Antoni van Leeuwenhoek Ziekenhuis
**Source(s) of monetary or material Support:** RT research

## Intervention

**Keyword:** MR-Linac, Radiotherapy

## Outcome measures

### Primary outcome

To test the feasibility of multiple techniques/software for MR-guided adaptive

radiotherapy on the Elekta Unity MRL system.

### Secondary outcome

Treatment associated >= grade 3 acute toxicity according to the NCI Common

Terminology Criteria of Adverse Events (CTCAE version 4.03).

# Study description

### Background summary

CE labelling of the Elekta Unity will mark the clinical start of MR-guided treatment of patients at the NKI-AVL. Within the Elekta workflow, software will be provided for registration and adaptation. To have full access to all our current functionality and meet our high standards of clinical practice, we intend to use the Elekta workflow as a starting point in which we will incorporate part of our currently used (XVI) software. Moreover, both Elekta and the NKI-AVL will expand the technical development of MR-guided radiotherapy after the clinical introduction and will gradually implement new software and techniques in the existing workflow for guidance and adaptation for further improvement. The proposed protocol aims to determine feasibility of multiple new techniques and software for MR-guided adaptive radiation therapy. For each proposed technique feasibility has to be determined individually.

### Study objective

Primary: To test the feasibility of multiple techniques / software for MR-guided adaptive radiation therapy on the Elekta Unity MRL.
Secondary: To register acute grade >= 3 toxicity.

### Study design

The proposed protocol is a prospective, non-randomized, basket- and umbrella

trial. Patients will be enrolled in multiple parallel cohorts, and will be treated with evolving techniques for treatment guidance and adaptation. Each new cohort will be defined by a tumor type(s) and a specific technical design/software program that will be added. Techniques that will be tested for feasibility in this protocol include, but are not limited to: XVI registration software, 4D MRI workflow for liver metastases, 4D MRI workflow for lung carcinomas, XVI multi-ROI registration, Library of Plan with manual plan selection for rectal carcinomas, Library of Plan for bladder carcinomas, and motion compensation by trailing. For each technique a specific study manual is available.

### Intervention

Radiotherapy

### Study burden and risks

The Elekta Unity MRL system is an investigational device with CE labeling and fully commissioned to be used clinically, that will develop continuously over time by implementation of new software by Elekta and by software developed at the NKI. It incorporates a 1.5 Tesla diagnostic-quality MRI scanner, manufactured by Philips Healthcare, which is integrated in the linear accelerator system. Technical feasibility of software for guidance and adaptation will be tested within the provided Elekta workflow. For each technical design or software product that will be tested a specific study manual will be available, including safety issues per technique.

## 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

• Patient, age >= 18 years, treated with radiation therapy on the MR-Linac.
• WHO performance 0-2.
• Ability to understand and the willingness to sign a written informed consent document.

## Exclusion criteria

• Contra*indications for an MRI examination.
• Patient is pregnant.
• Claustrophobia.
• Patients >140 kg and/or a body width > 60 cm.
• Patients with any other clinically significant medical condition which makes it undesirable for the patient to participate in the study or which could jeopardize compliance with study requirements or severe psychiatric illness/social situation.

# Study design

## Design

**Study type:** Interventional

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 23-01-2019 |
| Enrollment: | 140 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 24-08-2018 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 29-11-2018 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 10-05-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 03-12-2019 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 12-06-2020 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 15-10-2020 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO | |

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|---|---|
| Date: | 29-12-2020 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 11-02-2021 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 27-05-2021 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 05-09-2023 |
| 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 |
|---|---|
| CCMO | NL65953.031.18 |