ARIA

Published: 05-02-2025
Last updated: 22-05-2025

Primary objective: study the technical feasibility and safety to perform stereotactic radiotherapy on MR-linac for cT1-2 glottic cancer patients.Secondary objectives: monitor the patient safety, toxicity and tolerability of this...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57519

Source
Onderzoeksportaal

Brief title
ARIA

Condition

- Other condition

Synonym
Early-stage glottic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten)

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

The percentage of fractions successfully performed on MR-Linac and the safety of the treatment looking at grade 3 late toxicity.

Secondary outcome

Patient safety, toxicity and tolerability of this treatment concept.

Study description

Background summary

In order to decrease the number of radiotherapy fractions in cT1-2 stage glottic larynx cancer patients, a stereotactic approach on MR-Linac is proposed. This approach consists of 5 fractions (8.5 Gy/fx) instead of the conventional 25 fractions (2.4 Gy/fx).

Study objective

Primary objective: study the technical feasibility and safety to perform stereotactic radiotherapy on MR-linac for cT1-2 glottic cancer patients.
Secondary objectives: monitor the patient safety, toxicity and tolerability of this treatment concept.

Study design

Phase I feasibility study

Intervention

Patients who are able to meet the pre-treatment dose constraints will be treated with 5 fractions divided in 2-3 weeks. The primary tumor will be treated with 5x8.5 Gy (42.5 Gy). Doses on the laryngeal cartilages will be kept as low as reasonably possible. All fractions will be applied on MR-linac, which is a linear accelerator combined with an MRI (magnetic resonance imaging). The MR-linac facilitates the integration of MRI in the radiotherapy planning and treatment. This enables position and shape adaptation for the treatment plan of

each fraction.

Study burden and risks

Benefits:less treatment fractions (5 vs 25) with potentially an improved oncological outcome. Burdensome: treatment time on the MR-linac will be longer (max 60 min. vs 15 min per fraction).

Risks: higher doses on the larynx may potentially lead to a higher toxicity outcome. However, since we only include non-smoking patients that meet the pre-defined dose constraints, we expect to have reduced this risk.

Contacts

Scientific
Universitair Medisch Centrum Utrecht
M. de Ridder
Heidelberglaan 100
Utrecht 3584 CX
Netherlands
088 75 63022
Public
Universitair Medisch Centrum Utrecht
M. de Ridder
Heidelberglaan 100
Utrecht 3584 CX
Netherlands
088 75 63022

Trial sites

Trial sites in the Netherlands

Universitair Medisch Centrum Utrecht
Target size: 20

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Squamous cell carcinoma of the glottic larynx, cT1-2 N0M0 stage, indication for curative radiotherapie

Exclusion criteria

Concurrent chemotherapy or cetuximab, smoking at the time of treatment, patients unsuited for MRI-imaging, pre-treatment dosimetric constraints are not met, malignant tumor(s) at another site, previous malignancies in the HN region treated with surgery, chemotherapy or radiotherapy, age < 18 years, participation in another interventional study, mental or physical impairment causing the participant to be unable to fill out questionnaires

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	20

Duration:	25 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	24-04-2025
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	NL88385.041.25
Research portal	NL-009228