Feasibility of primer shot radiotherapy for non-small cell lung cancer (PRIMER)

Published: 29-07-2024
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To determine the safety and feasibility of primer shot fractionation for NSCLC.

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

Summary

ID

NL-OMON56897

Source
ToetsingOnline

Brief title
PRIMER

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Non-small cell lung cancer, non-small-cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Vanuit eigen RT-afdeling AVL

Intervention

Keyword: Feasibility, NSCLC, Radiotherapy, Reoxygenation

Outcome measures

Primary outcome

The main study endpoint is whether patients finish the radiotherapy schedule as planned (completion of all 5 fractions and two or less additional unplanned days between fractions).

Secondary outcome

Secondary endpoints are tumor response at the end of treatment and 3 months thereafter, and acute toxicity.

Study description

Background summary

Radiotherapy employs uniform, equally spaced weekday fractions that do not account for changes in tumor radiosensitivity. However, radiobiological characteristics evolve during the radiotherapy schedule as reoxygenation increases radiosensitivity. In tumor-response simulations and preclinical experiments, it was superior to prime the tumor with one radiotherapy fraction, followed by a treatment break permitting mitotic cell death and reoxygenation of tumor cells.

Study objective

To determine the safety and feasibility of primer shot fractionation for NSCLC.

Study design

A prospective non-randomized feasibility trial to test the safety of primer shot fractionation in a 3+4 phase with increasing treatment breaks, followed by an expansion cohort.

Intervention

All treatments are 5x6 Gy to all targets. Patients receive an increasing primer shot treatment break. In the 3+4 phase, the break between the first and the second radiotherapy fraction is: 1, 2 and 3 weeks. The maximum tolerated break

length will be used for the expansion cohort.

Study burden and risks

Based on simulations and preclinical data, primer shot treatment breaks increase tumor control. However, the increased overall treatment time could potentially increase the chance a patient drops out before the radiotherapy schedule is finished. Because of the gradually prolonged break, this risk is relatively small and acceptable for this population. Additionally, patients are asked to fill in PRO-CTCAE lung subset questionnaires at the start of treatment and during follow-up. They will also receive 1 additional CT with contrast at fraction 5.

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

• Age >= 18 years
• NSCLC (either pathology proven or sufficient clinical suspicion to be treated as NSCLC), referred for palliative radiotherapy of at least the primary tumor site (to eleviate or prevent symptoms like shortness of breath, coughing, pain or hemoptysis).
• NSCLC, stage 2-4
• WHO performance score 0*2.
• Provision of signed, written and dated IC prior to any study specific procedures.

Exclusion criteria

• Interstitial lung disease
• Treatment with vascular endothelial growth factor receptor (VEGFR) inhibitors
• Prior thoracic radiotherapy (>20 Gy EQD2 a/b 3) overlapping with the current planning target volume
• Pregnant

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2024
Enrollment:	35
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	29-07-2024
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	NL86077.041.24