Determination of peripheral immune cell activity during treatment with either surgery or radiotherapy in patients with early stage non-small cell lung cancer.

Published: 07-05-2013
Last updated: 26-04-2024

To study the effect of surgery and SABR on both immunostimulatory (with primary endpoint CD8 positive cells)and immunosuppressive cells in peripheral blood in patients with early stage non-small cell lung cancer who are treated with either modality…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON39912

Source
ToetsingOnline

Brief title
HAMLET study

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms
- Respiratory tract therapeutic procedures

Synonym
lung cancer, lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immunology, lung surgery, non-small cell lung carcinoma, radiotherapy

Outcome measures

Primary outcome

To determine whether an increase in CD8 activity can be observed in patients

with early stage lung cancer who undergo surgical intervention or SABR.

Secondary outcome

The number and activation status of CD4 positive cells, monocytes, Tregs and

MDSC in patients with early stage lung cancer undergoing curative intervention

(surgery or SABR).

Study description

Background summary

An anatomical surgical resection is considered to be the standard of care in fit patients who present with early stage non-small cell lung cancer (NSCLC). However, surgery is less frequently performed in both elderly patients (aged >=75 years), who represent the fastest-growing group of patients with stage I/II NSCLC, and in patients who have significant co-mobidity. Following the introduction of stereotactic ablative radiotherapy (SABR), an outpatient treatment that is typically delivered in between 3-8 fractions, the median survival of all elderly patients undergoing radiotherapy in The Netherlands increased by 9.3 months. Randomized trials comparing SABR and surgery have yet to be completed and results of the ongoing ACOSOG Z4032 studies will not be available in the within 5 years. A recent data retrospective study comparing both modalities has raised interesting questions about the impact of local therapy on recurrence patterns. It was found that a better loco-regional disease control rate was achieved with SABR.

Study objective

To study the effect of surgery and SABR on both immunostimulatory (with primary endpoint CD8 positive cells)and immunosuppressive cells in peripheral blood in patients with early stage non-small cell lung cancer who are treated with either modality.

Study design

The study will be conducted as a prospective multi centre observational pilot study of the *immune score* from histological biopsies or resection specimen in patients either treated with SABR or surgery. The study is not to compare both modalities, for which a randomised trial is needed, but to study the immune score before and after radiotherapy and surgery as a pilot study.

Study burden and risks

Only risks in participation are the risks with drawing blood. Subjects will not have any benefits. This pilot experiment will be used to generate data which may be explored in a larger series of patients.

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

- Cytologically or histologically proven cT1-2aN0M0 NSCLC
- Patients >= 18 years old
- Patients should be fit to undergo both treatments in accordance with institutional protocols

Exclusion criteria

- Patients with any sign of any co-existing infectious disease or immunosuppressive treatment (inhalation steroids are permitted)
- Mentally incapacitated subjects

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-09-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	07-05-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL42081.078.12