# Obtaining and analyzing plasmasamples from patients with non small cell lung cancer, referred for radiation treatment and/or chemotherapy

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The aim of this pilot study is to investigate the hypothesis that certain biomarkers of ICD that were identified in vitro or ex vivo are detectable in patient sera following radiotherapy and/or chemotherapy. Radiotherapy alone or concurrent...

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

## Summary

### ID

NL-OMON47175

**Source**
ToetsingOnline

**Brief title**
ICD

### Condition

- Miscellaneous and site unspecified neoplasms benign

**Synonym**
non small cell lung cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** MAASTRO clinic

**Source(s) of monetary or material Support:** MAASTRO clinic

## Intervention

**Keyword:** Lung cancer, Non small cell, Plasma

## Outcome measures

### Primary outcome

Changes of relative protein expression / lipid profile for plasma /

plasma-derived exosomes, linked to ICD

### Secondary outcome

- Changes of relative protein expression, linked to Th1 / Th2 subsets

- Changes of relative protein expression, linked to vascular damage

# Study description

### Background summary

The main aim of anticancer therapies is to exert cytotoxic effects on cancer cells. Most contemporary anticancer therapies kill cancer cells through a non-immunogenic pathway of cell death and are thus unable to *revive* and mediate anticancer immune responses. However, it recently emerged that some anticancer therapeutic modalities are capable of inducing a cell death subroutine called immunogenic cell death (ICD) that can mediate specific, sustained anticancer immunity (1). These observations have marked the beginning of intense research into immunoadjuvant or anticancer immunity inducing *side-effects* associated with anticancer therapies.
No published data about human biomarkers for ICD is available.
Recently it has emerged that ICD may also be associated with a *viral response-like chemokine signature (VCS)* capable of acting as both *find me* signal (for granulocytic myeloid cells) and *keep away* signal (for immature monocytic myeloid cells) - further details of this paradigm are under investigation (8).
ICD has been found to be associated with several immune effector signatures (mainly defined as such, for predominantly solid cancers) including positive dendritic cell (DC) maturation (phenotypic and function) and positive regulation of T cell immunity (proliferation and Th1 polarization-type cytokine signature) (10).

The presence of determinants of ICD can be confirmed through the strategy of following biomarkers (in non-hematological cancers)
We will also investigate serum-associated exosomes as possible biomarkers of an efficient antitumor response. A secondary endpoint is defined as the cytokine profile that is linked to a Th1 or Th2-phenotype. A third endpoint consists of detecting signs of cardiovascular damage with known myocardial markers and vascular markers. This endpoint is tied to the effects of radiation therapy on the cardiovascular system. We need to stress that the mentioned lists of potential biomarkers is non-exhaustive, as this rapidly evolving field might steer us into a new direction while the study is ongoing. We will keep up with literature and will implement new biomarker targets into our panel as required.

## Study objective

The aim of this pilot study is to investigate the hypothesis that certain biomarkers of ICD that were identified in vitro or ex vivo are detectable in patient sera following radiotherapy and/or chemotherapy. Radiotherapy alone or concurrent cisplatin-doublet and radiotherapy will be investigated. We will conduct this pilot study to gather initial data to build upon in future clinical trials, as there is no in vivo data available on this topic.

## Study design

40 patients will have a bloodwithdrawal of 25 ml at three points during their treatment:

For concurrent CT/RT
- Immediately before the first fraction of RT
- Immediately before the third fraction of RT (commonly 48h)
- Immediately after the last or second-to-last fraction of RT

For RT only:
- Immediately before the fraction of RT
- Immediately before the second fraction of RT (commonly 48h)
- Immediately after the last fraction of RT

## Intervention

3 blood withdrawals of 25ml

## Study burden and risks

The burden consists of 3 extra blood withdrawals of 25 ml, with the minimal

risk of damage to a vein or nerve.

## Contacts

**Public**
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

• Participant is willing and able to give informed consent for participation in the trial.
• Male or female, aged 18 years or above.
• Diagnosed with non-small cell lung cancer
• Scheduled to receive one of the following two therapeutic strategies:
- Concurrent cisplatin-doublet chemotherapy and radiotherapy (minimal dose of 60 Gy in fractionated non-ablative doses) in patients with stage III NSCLC
- SBRT for stage I NSCLC: 54Gy in 3 fractions, 48 Gy in 4 fractions or 60 Gy in 8 or 5 fractions
• Is able and willing to comply with all trial requirements.

### Exclusion criteria

- Chronic use of corticosteroids, except when used as anti-emetics for chemotherapy or inhalers
- NSAIDs taken until 5 days before radiotherapy or during radiation (low dose Aspirin at a maximum of 160 mg/day, is allowed)
- Active auto-immune diseases
- Immunosuppressive medication

## Study design

### Design

**Study type:** Interventional

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-04-2017 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 23-03-2017 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

## 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 | NL59321.068.16 |