# A diagnostic Study of European and Japanese advanced NSCLC patients to evaluate suitable sample types for EGFR testing: The ASSESS Study

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This study will investigate if it is possible to perform the EGFR mutation test using blood samples. If successful, this study may mean that in the future, the mutation test can be done using a blood sample, and that patients may not need to have...

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

## Summary

### ID

NL-OMON38725

**Source**
ToetsingOnline

**Brief title**
ASSESS

### Condition

- Miscellaneous and site unspecified neoplasms benign
- Respiratory tract neoplasms

**Synonym**
lung cancer

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Astra Zeneca
**Source(s) of monetary or material Support:** Industry : AstraZeneca

## Intervention

**Keyword:** advanced NSCLC, diagnostic Study, EGFR testing, sample types

## Outcome measures

### Primary outcome

The study will establish whether blood (plasma) is a suitable sample type for reliably determining the EGFR mutation status of patients with NSCLC compared with cytology/tumour tissue.

### Secondary outcome

In addition the study will also collect information about NSCLC, result of the EGFR mutation test, how the EGFR mutation test is performed in the laboratory, and what effect the EGFR mutation test result has on the choice of drugs used to treat NSCLC.

# Study description

### Background summary

On the surface of most lung cancer cells there are proteins (receptors) called Epidermal Growth Factor Receptors (EGFR) that play an important role in causing many tumours to grow. A specific change to the DNA of EGFR, called a so-called *EGFR mutation*, makes cancer cells more or less likely to respond to anti-cancer drugs. Some hospitals perform a test to see whether the EGFR mutation is present in the tumour or not in order to determine what drugs will be more effective in treating the lung tumour.

The EGFR mutation test is usually performed on the tumour sample which was used to diagnose your lung cancer. The tumour sample is obtained by procedures that are often invasive or uncomfortable for some patients. This study will

investigate if it is possible to perform the EGFR mutation test using blood samples. If successful, this study may mean that in the future, the mutation test can be done using a blood sample, and that patients may not need to have repeated sampling with uncomfortable of invasive procedures.

### Study objective

This study will investigate if it is possible to perform the EGFR mutation test using blood samples. If successful, this study may mean that in the future, the mutation test can be done using a blood sample, and that patients may not need to have repeated sampling with uncomfortable of invasive procedures.

### Study design

You will be asked to provide a tumour/cytology sample that has been used to diagnose your Non Small Cell Lung Cancer (NSCLC); a new biopsy will not be required. In addition you will also be asked to provide a blood sample. Both samples will be used for EGFR mutation testing. You will also be given the option to consent to provide an optional additional tissue/cytology sample or remaining material from the tumour/cytology sample used for your EGFR mutation test for exploratory biomarker research

### Study burden and risks

The study does not involve more visits to the hospital than those scheduled in clinical practice to a patient with your disease.

The unique difference will be that you will be asked to donate an additional blood sample of 10 ml within one of the routine blood extractions organised by your doctor for the management of your disease.

## Contacts

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Astra Zeneca

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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Provision of written informed consent.
- Patients aged 18 years and older from European countries and patients aged 20 years and -older for patients from Japan.
- Histological or cytological confirmed locally advanced NSCLC (stage IIIA/B) not suitable for curative treatment or metastatic (stage IV) NSCLC.
- Newly diagnosed patients with locally advanced and/or metastatic NSCLC who are systemic treatment Naïve (i.e. no chemotherapy or EGFR-TKI) or patients with recurrent disease who have previously received adjuvant chemotherapy (not including EGFR-TKI).
- Provision of diagnostic cancer tissue or cytology sample upon inclusion (surgical specimen, biopsy sample, or cytology sample is acceptable).
- Provision of a routine blood (plasma) sample.

## Exclusion criteria

- Involvement in the planning and/or conduct of the study (applies to both AstraZeneca staff and/or staff at the study site)
- Previous enrolment in the present study
- As judged by the investigator, any evidence of severe or uncontrolled systemic disease (e.g. unstable or uncompensated respiratory, cardiac, hepatic or renal disease)
- Evidence of any other significant clinical disorder or laboratory finding that made it undesirable for the patient to participate in the study.
- Pregnancy or breast-feeding

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-12-2013 |
| Enrollment: | 120 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 01-10-2013 |
| Application type: | First submission |
| 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 | NL44686.078.13 |