

Lay Protocol Synopsis

Lay language title:	Understanding treatments and quality of life in adults living with metastatic non-small cell lung cancer with BRAF ^{V600E} mutation – OCTOPUS study
Full study title:	Observational study describing diagnosis and treatment patterns in adults with metastatic non-small cell lung cancer with BRAF ^{V600E} mutation in clinical practice, to assess treatment effectiveness and quality of life – OCTOPUS study
Registry Number:	NCT05546905

1 What is the reason for the study?

Non-small cell lung cancer is the most common type of lung cancer, making up about 80% to 85% of all cases. A small number of people with this cancer, around 1-2%, have a change in their DNA called the BRAF^{V600E} mutation. When the BRAF gene is mutated, it produces an over-active BRAF protein that tells the cells to continuously grow and divide, leading to cancer.

There is still limited information about how people with this rare form of non-small cell lung cancer are diagnosed and treated in everyday clinical practice. Learning from the experiences of patients who already have this condition can help improve care for future patients.

This study looks at how doctors treat people living with metastatic* non-small cell lung cancer with the BRAF^{V600E} mutation. It aims to describe the treatments commonly used, how well these treatments work, and how people’ quality of life may be affected, when information is available.

* Metastatic means the cancer has spread from the lungs to other parts of the body.

2 What are the objectives of the study?

The main objective of this study was to describe how doctors usually treat adults living with metastatic non-small cell lung cancer with the BRAF^{V600E} mutation. In particular, the study looked at the treatments received after diagnosis of the metastasis and the treatments given in case of progression of the disease or in case of low tolerability.

The study also aimed to:

- look at all the treatments received in case of progression of the cancer or in case of low tolerability
- describe the characteristics of people (such as age, sex, and medical details)
- assess how long people lived after the start of the treatments
- assess whether their quality of life changed during treatment, using questionnaires in some patients
- describe any side effects during treatment. Side effects are unwanted medical events that may or may not be caused by treatment used
- explain how and when doctors tested for the BRAF mutation.

3 How is the study conducted?

This was an observational study. This means doctors watched what happened as part of normal care, without changing or influencing treatment choices.

This study took place in France, Germany, Italy, Spain and the United Kingdom.

Adults with metastatic non-small cell lung cancer, with the BRAF^{V600E} mutation, who started their first treatments from December 2017, were invited to participate. People followed their usual care. Some filled out quality of life questionnaires during the study.

No extra tests or visits were required for the study.

4 Who can take part in the study?

The following people could participate in the study:

- Aged 18 or older when the first treatments for metastatic non-small cell lung cancer are started
- With BRAF^{V600E} mutation confirmed by adequate testing
- Starting first treatments for metastatic non-small cell lung cancer, with the BRAF^{V600E} mutation, from December 2017
- Agreed to participate and allow their data to be used according to local rules
- Not participating in another study for metastatic non-small cell lung cancer.

5 What are the study treatments and how are they administered?

The study did not provide, request, or require any specific or experimental treatment.

Doctors chose the treatment, as part of normal medical practice.

The study simply collected information about the treatment chosen and about what happened after the treatment began.

6 Ethical considerations

The study was carried out in accordance with ethical guidelines and research regulations. It began only after getting official approval. People agreed voluntarily to take part in the study.

7 What are the possible benefits and risks in taking part in the study?

Taking part in this study was voluntary and had no impact on the treatment.

There were no additional risks or no direct benefit for participants. However, the study's findings could contribute in improving the knowledge of treatments for a lung cancer.