

# A study to test afatinib in people aged 70 years or older who have advanced non-small cell lung cancer (NSCLC) with EGFR mutations

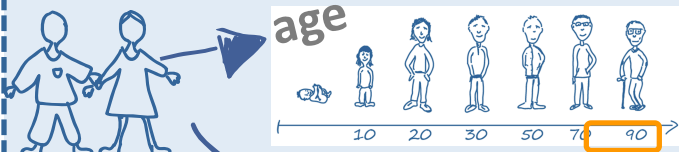
Afatinib is used to treat certain types of lung cancer with changes in EGFR genes. Elderly people are often less able to tolerate therapies than younger people.

This **study** was to find out:



How well do **elderly** participants with certain types of NSCLC **tolerate afatinib**?

**Participants had advanced NSCLC and certain changes in EGFR genes. They had to be 70 years or older.**



14  
women

11  
men

There were **25 participants** from **the United States**.

Each participant took each day

1  30 mg Afatinib

The dose could be reduced if the participants could not tolerate the 30 mg dose.

All participants who took afatinib had **unwanted effects**.



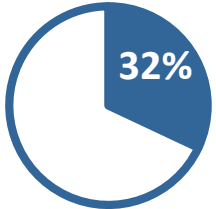
The most common unwanted effect was diarrhoea (88% of participants).

## RESULTS

8 of 25 participants (32%) needed to **reduce their afatinib dose** because they could not tolerate the dose.

Participants with reduced dose

32%



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## A study to test afatinib in people aged 70 years or older who have advanced non-small cell lung cancer (NSCLC) with EGFR mutations

This is a summary of results from one clinical study.

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We thank all study participants. You helped us to answer important questions about afatinib and the treatment of advanced NSCLC.

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### What was this study about?

The purpose of the study was to find out how well elderly people with certain types of advanced NSCLC could tolerate afatinib. Elderly people are often less able to tolerate therapies than younger people. Afatinib is used to treat certain types of lung cancer that grow because of changes to the EGFR gene. Afatinib works by blocking growth signals like EGFR. We wanted to see if using afatinib also helps elderly people with NSCLC who have changes to the EGFR gene.



### Who took part in this study?

Elderly participants with advanced NSCLC that had certain changes in EGFR genes could be in this study. Participants needed to be 70 years of age or older.

25 participants took part in the study. This included 11 men and 14 women. The youngest participant was 71 years old and the oldest participant was 93 years old. The average age of the participants was 79 years.

This study took place in the United States.



### How was this study done?

All participants in the study were assigned to take 30 mg of afatinib once a day. The dose could be reduced if the participants could not tolerate the 30 mg dose. We wanted to know how many participants needed to have their dose reduced.

Afatinib is a tablet that is taken by mouth. The participants and doctors knew what dose the participants were taking.

Participants could be in the study until their cancer got worse or they and their doctor decided to stop participating.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health.



### What were the results of this study?

8 of the 25 participants (32%) had their dose of afatinib reduced because they could not tolerate the 30-mg dose. The reasons for the dose reductions were diarrhoea, indigestion (dyspepsia), fatigue, inability to perform tasks (performance status decreased), toe nail or finger nail infection (paronychia), thickening of the skin (hyperkeratosis), and peeling skin (skin exfoliation). These events may have been caused by afatinib or some other cause.










### Did participants have any unwanted effects?

Yes, participants taking afatinib had unwanted effects. Unwanted effects are health problems that the doctors think were caused by afatinib.

In this study, all 25 of the participants had unwanted effects.

The table below shows the most common unwanted effects. The table also shows how many participants had each of these unwanted effects.

Type of unwanted effect	Afatinib 30 mg 25 participants	
Diarrhoea	22 participants (88%)	
Rash	14 participants (56%)	
Dry skin	13 participants (52%)	
Inflamed and sore mouth (stomatitis)	9 participants (36%)	
Fatigue	9 participants (36%)	
Dry mouth	8 participants (32%)	

Some unwanted effects were serious because they required a stay in hospital or a longer stay in hospital. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, 1 participant (4%) had serious unwanted effects.



## Where can I find more information about this study?

You can find further information about this study at these websites:

1. Go to <http://www.trials.boehringer-ingelheim.com/> and search for the study number 1200.209.
2. Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search for the NCT number NCT02514174.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A Single Arm Phase IV Study of Afatinib in Elderly Patients with recurrent or Stage IV Non-Small Cell Lung Cancer (NSCLC) Whose Tumors Have Common Epidermal Growth Factor Receptor (EGFR) mutations (Exon 19 Deletions or Exon 21 L858R Substitution Mutations)'.

This was a Phase IV study. This study started in February 2016 and finished in April 2019.



## Are there additional studies?

If we do more clinical studies with afatinib, you will find them on the websites listed above. To search for these studies, use the word afatinib.

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### Important notice

This lay summary is provided as part of Boehringer Ingelheim's commitment to publicly share clinical study results.

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Other studies may have different results. Usually, more than one study is carried out to find out how well a medicine works and to determine the side effects of a medicine.

This lay summary may include uses, formulations, or treatment regimens for the medicine studied that may be approved or not approved in your country. This lay summary is not intended to promote any product or indication, to guide treatment decisions, or to replace the advice of a healthcare professional.

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