A study to test whether different doses of BI 655064 help people with active lupus nephritis

Boehringer Ingelheim

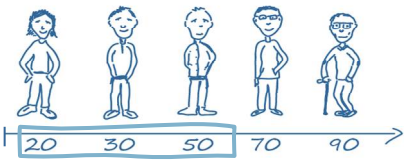
Lupus nephritis is kidney inflammation caused by the autoimmune disease lupus. The inflammation can be severe, leading to loss of kidney function.

This **STUDY** was done to find out:

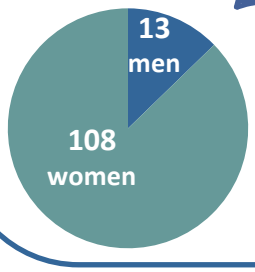
Does a medicine called **BI 655064** help people with **lupus nephritis**?

Participants…

✔ had lupus nephritis



18 – 62 years old



There were **121 participants** from **Asia, Australia, Europe** and **North America.**

Participants received treatment as injection under the skin.

They were divided into 4 groups:

low dose of BI 655064

or

medium dose of BI 655064

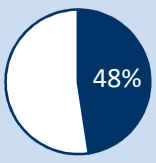
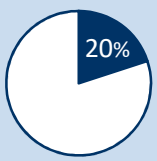
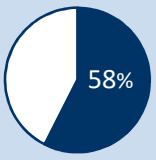
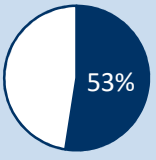
or

high dose of BI 655064

or

Placebo injection, *which didn't contain any medicine*

Participants in all groups had **unwanted effects**.

low dose of BI 655064	**medium** dose of BI 655064	**high** dose of BI 655064	**Placebo**
			
10 out of **21** participants	**4** out of **20** participants	**23** out of **40** participants	**21** out of **40** participants

RESULTS

We found that after 1 year (52 weeks), **none** of the doses of BI 655064 **worked better than placebo** to improve kidney function.

In an unplanned analysis after the trial, we found that the higher doses of BI 655064 worked better at improving kidney function compared with placebo when the improvement was confirmed at both 46 and 52 weeks.

Study: 1293-0010

A study to test whether different doses of BI 655064 help people with active lupus nephritis

This is a summary of results from 1 clinical study.

We thank all study participants. You helped us to answer important questions about BI 655064 and the treatment of lupus nephritis.

What was this study about?

The purpose of this study was to find out whether a medicine called BI 655064 helps people with lupus nephritis. Lupus nephritis is kidney inflammation caused by the autoimmune disease lupus. The inflammation can be severe, leading to loss of kidney function. New treatments are needed for this condition. BI 655064 is a medicine that is being developed to treat people with autoimmune disorders. When we develop a new medicine, we need to make sure it works. We wanted to see if different doses of BI 655064 help improve kidney function in people with lupus nephritis.

Who took part in this study?

Adults with lupus nephritis could take part in this study.

121 participants were treated in the study. 108 (89%) were women and 13 (11%) were men. The average age was 35 years. The youngest participant was 18 years old. The oldest participant was 62 years old.

The following table shows the numbers of participants in the study in different regions.

Region	Countries	Number of Participants
Asia and Australia	Australia, Hong Kong, Japan, Malaysia, Philippines, South Korea, Thailand	51
Europe	Czech Republic, France, Germany, Greece, Italy, Poland, Portugal, Serbia, Spain, United Kingdom	46
North America	Canada, Mexico, United States	24

How was this study done?

Participants were divided into 4 groups:

- Low dose BI 655064 group
- Medium dose BI 655064 group
- High dose BI 655064 group
- Placebo group

Participants received study treatment as an injection under the skin. Placebo injections looked like BI 655064 but did not contain any medicine.

Participants and doctors did not know in which group the participants were. Throughout the study, participants also received standard medication for lupus nephritis.

In this study, we wanted to see if BI 655064 helps to improve the participants' kidney function. To find out, we did urine and blood tests to see how well the kidneys were working. We did these tests before participants started receiving BI 655064 or placebo, while they were receiving it, and after they had been receiving it for a year. We compared the results among the treatment groups.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health. Participants were in the study slightly over a year.

What were the results of this study?

We found that after 1 year (52 weeks), none of the doses of BI 655064 worked better than placebo to improve kidney function. However, the placebo group had a much higher than expected improvement in kidney function.

In an unplanned analysis after the trial, we found that the higher doses of BI 655064 worked better at improving kidney function compared with placebo when the improvement was confirmed at both 46 and 52 weeks.

Did participants have any unwanted effects?

Yes, participants in all groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by BI 655064 or placebo. In this study:

- 10 out of 21 participants (48%) who took the low BI 655064 dose had unwanted effects.
- 4 out of 20 participants (20%) who took the medium BI 655064 dose had unwanted effects.
- 23 out of 40 participants (58%) who took the high BI 655064 dose had unwanted effects.
- 21 out of 40 participants (53%) who took placebo 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	BI 655064			Placebo
	Low dose (21 participants)	Medium dose (20 participants)	High dose (40 participants)	Placebo (40 participants)
Upper respiratory tract infection	1 participant (5%)	2 participants (10%)	5 participants (13%)	4 participants (10%)
Shingles (herpes zoster)	1 participant (5%)	0 participants	4 participants (10%)	1 participant (3%)
Injection site pain	2 participants (10%)	0 participants	3 participants (8%)	0 participants
Reduced number of lymphocytes, a type of white blood cell (lymphopenia)	0 participants	0 participants	3 participants (8%)	1 participant (3%)
Increased weight	0 participants	0 participants	3 participants (8%)	0 participants

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, 2 participants (10%) in the low BI 655064 dose group had serious unwanted effects. 1 participant (5%) in the medium BI 655064 dose group had serious unwanted effects. 5 participants (13%) in the high BI 655064 dose group had serious unwanted effects. 3 participants (8%) in the placebo group 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.mystudywindow.com and search for the study number 1293-0010**.**
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2015-001750-15.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02770170**.**

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A double-blind, randomised, placebo-controlled trial evaluating the effect of BI 655064 administered as subcutaneous injections, on renal response after one year of treatment, in patients with active lupus nephritis'.

This was a Phase II study. This study started in August 2016 and finished in August 2020.

Are there additional studies?

If we do more clinical studies with BI 655064, you will find them on the websites listed above. To search for these studies, use the phrase BI 655064.

Some people with lupus nephritis who took part in this study with BI 655064 and showed clinical improvement were able to take part in study 1293-0013, an additional study with BI 655064.

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.

You should not change your therapy based on the results of this study. Always consult with your treating physician about your therapy.