A study to test how effective and safe BI 655130 is in people with the skin disease palmoplantar pustulosis (1368.15)

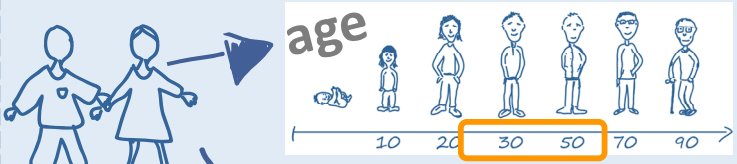
Boehringer Ingelheim

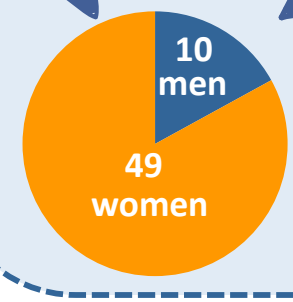
Palmoplantar pustulosis (PPP) is a skin disease. It causes blisters filled with pus to appear on the palms of the hands and soles of the feet.

This **study** was to find out:

Does a medicine called **BI 655130** help people with **palmoplantar pustulosis** and how well do they tolerate different doses of BI 655130? BI 655130 is also called Spesolimab.

Participants who took part had palmoplantar pustulosis





59 participants from **6 countries** from Germany, Canada, Denmark, Italy, Spain and Sweden took part.

Each participant received an infusion into a vein 4 times in 16 weeks:

300 mg BI 655130

or

900 mg BI 655130

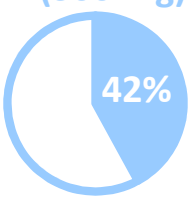
or

Placebo

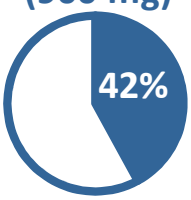
(An infusion that did not contain a medicine)

42% of participants who took BI 655130 and 43% of participants who took placebo had **unwanted effects.**

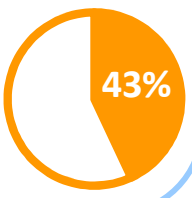
BI 655130 (300 mg)



BI 655130 (900 mg)



Placebo



RESULTS

We found that there was no difference between groups. The improvement of palmoplantar pustulosis of participants who took BI 655130 and participants who took placebo was similar. When we later looked in more detail, we found that symptoms appeared to improve more for a certain group of participants taking BI 655130 than for participants who took placebo.

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A study to test how effective and safe BI 655130 is in people with the skin disease palmoplantar pustulosis

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about BI 655130 and the treatment of palmoplantar pustulosis.

What was this study about?

The purpose of this study was to find out whether a medicine called BI 655130 (spesolimab) helps people with palmoplantar pustulosis. We also wanted to see how well they tolerated different doses of BI 655130.

Palmoplantar pustulosis (PPP) is a skin disease. It causes blisters filled with pus to appear on the palms of the hands and soles of the feet. Palmoplantar pustulosis is often difficult to treat. The symptoms can come and go; there is currently no cure. Palmoplantar pustulosis can be very painful and can make using the hands or walking difficult. New treatments for palmoplantar pustulosis are needed.

Who took part in this study?

59 people with palmoplantar pustulosis took part in this study. This included 49 women and 10 men. The youngest participant was 22 years old and the oldest participant was 64 years old. The average age was 50 years.

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

Country	Number of Participants
Germany	25
Canada	14
Denmark	10
Italy	6
Spain	2
Sweden	2

How was this study done?

At the start of the study, doctors checked whether people were suitable. If people were suitable, they had to wait between 1 and 4 weeks before they started the study.

Participants were divided into 3 groups of almost equal size. Every participant had an equal chance of being in any of the groups. Participants were given 4 infusions of BI 655130 or placebo into a vein 4 times in 16 weeks. The groups were:

- 300 mg BI 655130 group
- 900 mg BI 655130 group
- Placebo group

Placebo infusion looked like BI 655130 but did not contain any medicine. We compared BI 655130 with placebo to find out how well BI 655130 works.

Participants and doctors did not know in which group the participants were.

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

This study was looking for information about 2 different things. These are described separately below and in the following section.

Does BI 655130 help participants with palmoplantar pustulosis more than placebo?

We wanted to see if BI 655130 helps participants with palmoplantar pustulosis more than placebo. To do this, we compared participants' symptoms before they took BI 655130 and 16 weeks later. We also measured how much of a participant's skin was covered by palmoplantar pustulosis before taking BI 655130 and 16 weeks later. We also made these comparisons for participants taking placebo. We wanted to see if participants who took BI 655130 showed improvement and compare this to any improvement shown by participants who took placebo.

Will participants have any unwanted effects?

We wanted to know if participants had any unwanted effects. Unwanted effects are health problems that the doctors think were caused by BI 655130 or placebo.

What were the results of this study?

Did BI 655130 help participants with palmoplantar pustulosis more than placebo?

We found that there was no difference in improvement of palmoplantar pustulosis between participants who took BI 655130 and participants who took placebo. Symptoms improved for a similar proportion of participants in all groups.

After the end of the study, we looked at the results in more detail. We found a certain group of participants taking BI 655130 whose symptoms appeared to improve more than those for participants who took placebo. The improvement was seen in participants whose symptoms were not getting better in the 1 to 4 weeks before they started taking BI 655130 or placebo.

Did participants have any unwanted effects?

Yes, participants in all groups had unwanted effects. In this study, 8 out of 19 participants (42%) in the 300 mg BI 655130 group had unwanted effects. 8 out of 19 participants (42%) in the 900 mg BI 655130 group had unwanted effects. 9 out of 21 participants (43%) in the placebo group 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 655130 300 mg 19 participants**	**BI 655130 900 mg 19 participants**	**Placebo 21 participants**
Common cold (nasopharyngitis)	1 participant (5%)	4 participants (21%)	2 participants (10%)
Headache	0 participants	4 participants (21%)	4 participants (19%)
Stuffy nose (rhinitis)	1 participant (5%)	1 participant (5%)	2 participants (10%)
Acne	0 participants	2 participants (11%)	0 participants

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital. None of the participants in the BI 655130 group had serious unwanted effects. 1 participant in the placebo group had a serious unwanted effect.

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 1368.15.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2016-004573-40.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03135548.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'Multi-center, double-blind, randomised, placebo-controlled, phase IIa study to investigate efficacy, safety, tolerability, pharmacokinetics and pharmacogenomics of multiple intravenous doses of BI 655130 in patients with Palmoplantar Pustulosis (PPP)'.

This study started in June 2017 and finished in November 2018.

Are there additional studies?

If we do more clinical studies with BI 655130, you will find them on the websites listed above. To search for these studies, use the word BI 655130.

Important notice

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

You should not change your therapy based on the results of this study without first talking to your treating physician. Always consult your treating physician about your specific therapy.

Boehringer Ingelheim has provided this lay summary in accordance with European Union transparency obligations.

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