

Safety and effectiveness of apremilast in people with plaque psoriasis

Date of summary: 26 February 2018

Study summary:

- This study looked at apremilast (a-PRE-me-last), a new treatment under investigation for psoriasis.
- After about 4 months, more people who took apremilast had improved psoriasis symptoms compared to people who took a dummy drug (placebo).
- Some people taking apremilast had side effects at the start of treatment. The most common side effects were diarrhoea, feeling sick, infections and headaches. These usually improved after two weeks.

A phase 3, multicenter, randomized, double-blind, placebo-controlled, efficacy and safety study of apremilast (CC 10004) in subjects with moderate to severe plaque psoriasis

EU Study Number: EudraCT 2010-019991-55
Other identifiers: NCT01194219
Study ID: CC-10004-PSOR-008

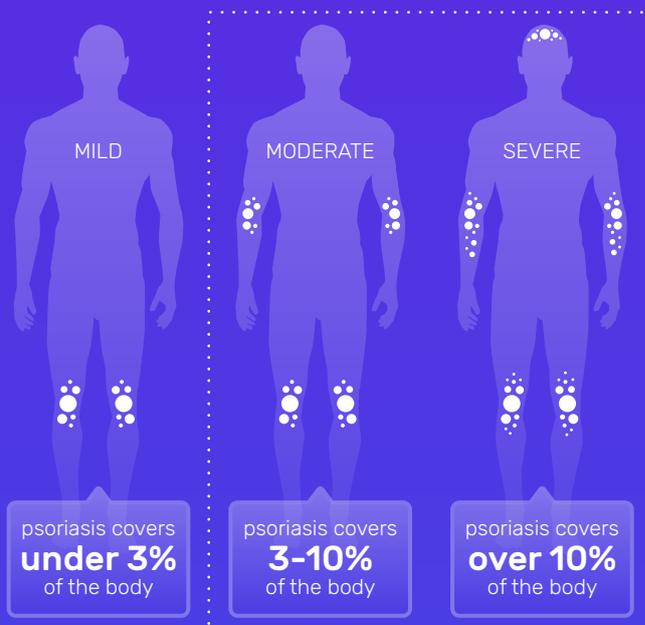
In a phase 3 study, a large group of people receive a new treatment to see if it is safe and effective. This summary shows the main results of a phase 3 study comparing apremilast with a placebo in people with psoriasis.

Why did the study take place?

- Plaque psoriasis is the most common form of psoriasis. Red, flaky patches (plaques) of extra skin cells build up on the skin surface. These itchy and painful patches usually form on the elbows, knees and scalp.
- The current treatments for psoriasis do not work for everyone. So more treatment options are needed.

What was the aim of the study?

- To see if apremilast can improve symptoms in people with **moderate to severe** plaque psoriasis.
- To see how safe apremilast is for these people.



Who took part in the study?

844 The study included **844 people**, Their average age was **46**

68 in every 100 people who took part were men

72 CENTRES TOOK PART IN:

Australia, Belgium, Canada, France, Germany, Italy, United Kingdom and United States



WHO COULD TAKE PART

People aged 18 years or older who had plaque psoriasis for more than 1 year



WHO COULD NOT TAKE PART

People with uncontrolled conditions such as heart problems, infections or cancer

People who had already taken apremilast

Please visit the website:

<https://clinicaltrials.gov/ct2/show/NCT01194219> for more details on why people could or could not take part in this study.

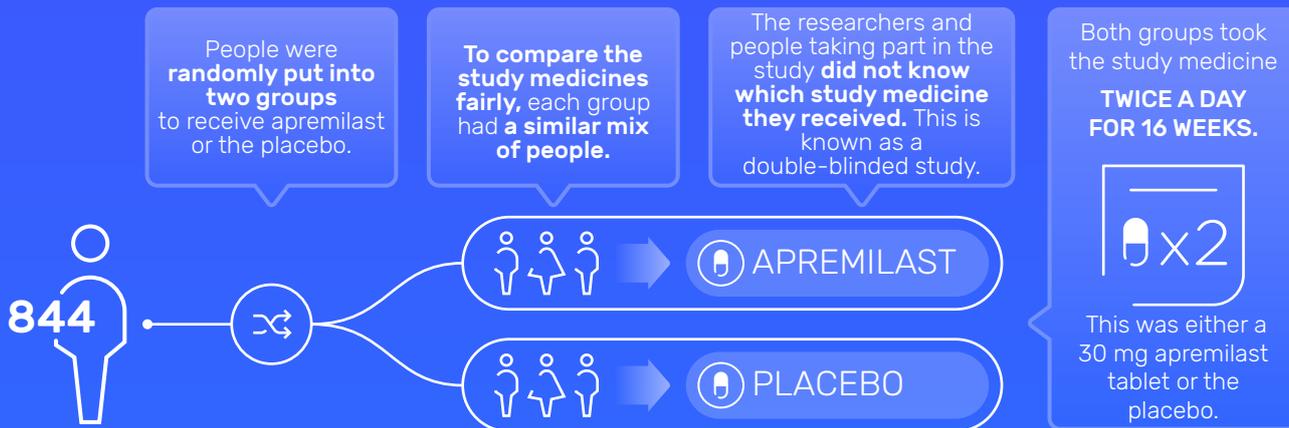


STUDY START DATE:
22 SEPTEMBER 2010



STUDY END DATE:
2 NOVEMBER 2011

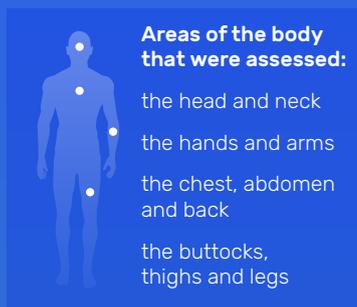
What medicines did people receive?



What were the main results of the study?

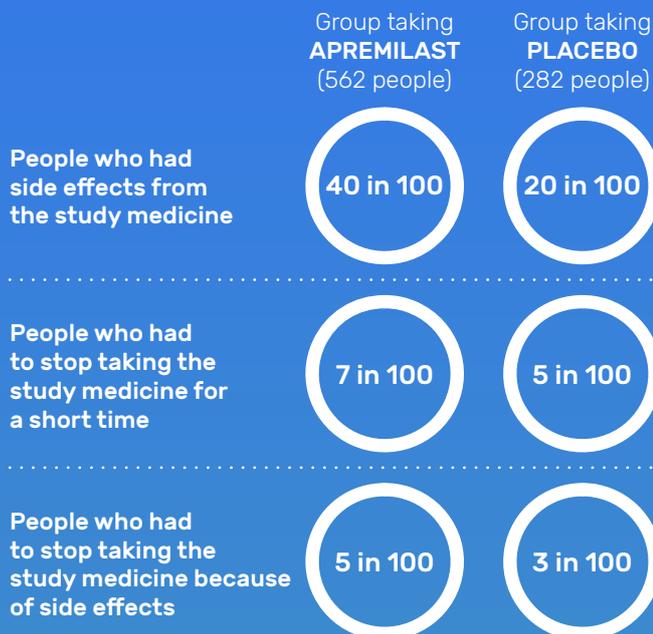
More people taking apremilast had improved symptoms of psoriasis compared with people taking the placebo

- Researchers assessed the skin in four parts of the body. They looked at how much of the skin had psoriasis patches. They also assessed how red, scaly and thick the patches were.
- The research team compared psoriasis symptoms at the start of the study and after 16 weeks of treatment.



Were there any side effects?

- Many medicines cause unwanted side effects.
- In a clinical study, the doctor records any side effects that might be caused by the study medicine.
- In this study, the research team compared the number of people with side effects in both treatment groups.
- More people taking apremilast had side effects than people taking the placebo.
- Most people were able to take the study medicine twice every day during the study. But more people taking apremilast had to take a break or stop treatment altogether.



What were the most common side effects of apremilast?

Common side effects that occurred more often with apremilast than placebo:



DIARRHOEA



FEELING SICK
(NAUSEA)



INFECTIONS OF THE NOSE,
SINUSES AND THROAT



HEADACHES

How long did these side effects last?

Most of them were **mild or moderate**. They lasted for **LESS THAN 2 WEEKS**

They were **LESS COMMON** after the first week of treatment

Were there any deaths in this study?

- One person taking apremilast died from heart failure during this study. The study doctor thought this was due to taking apremilast. Future studies of apremilast will be done to confirm its safety.
- One person taking the placebo took their own life during this study. The study doctor did not think this was due to the study treatment.

How will this study benefit patients?



This study found that apremilast may improve symptoms for some people with psoriasis.

- One study is not enough to find out if a new medicine works.
- Other studies may find different results than those in this report.
- Several studies must be done to prove that a new medicine is safe and effective.

How to use this summary to help patients and doctors talk about this research

- **Question from patient to doctor:** How important is this research to my care?
- **Question from doctor to patient:** How relevant is this research to what matters most to you?

Are there any plans for future studies?

- This is an ongoing study. The safety and effectiveness of apremilast will be measured for up to four more years.
- The results from these future studies will show if apremilast is safe to use:
 - Over a longer time period.
 - In different people.

Who sponsored this study?

Celgene Corporation (Corporate Headquarters)

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Celgene would like to thank all of the people who participated in this study.

Further information

To find out more information on this study, please visit:

- <https://clinicaltrials.gov/ct2/show/NCT01194219>

To find out more information on clinical studies in general, please visit:

- <https://www.clinicaltrials.gov/ct2/about-studies/learn>
- <http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>