What is the longer-term safety of ritlecitinib when used to treat patients aged 12 years or older with alopecia areata?

THE FULL TITLE OF THIS ARTICLE IS:

Integrated safety analysis of ritlecitinib, an oral JAK3/TEC family kinase inhibitor, for the treatment of alopecia areata from the ALLEGRO clinical trial program

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WHAT IS ALOPECIA AREATA?

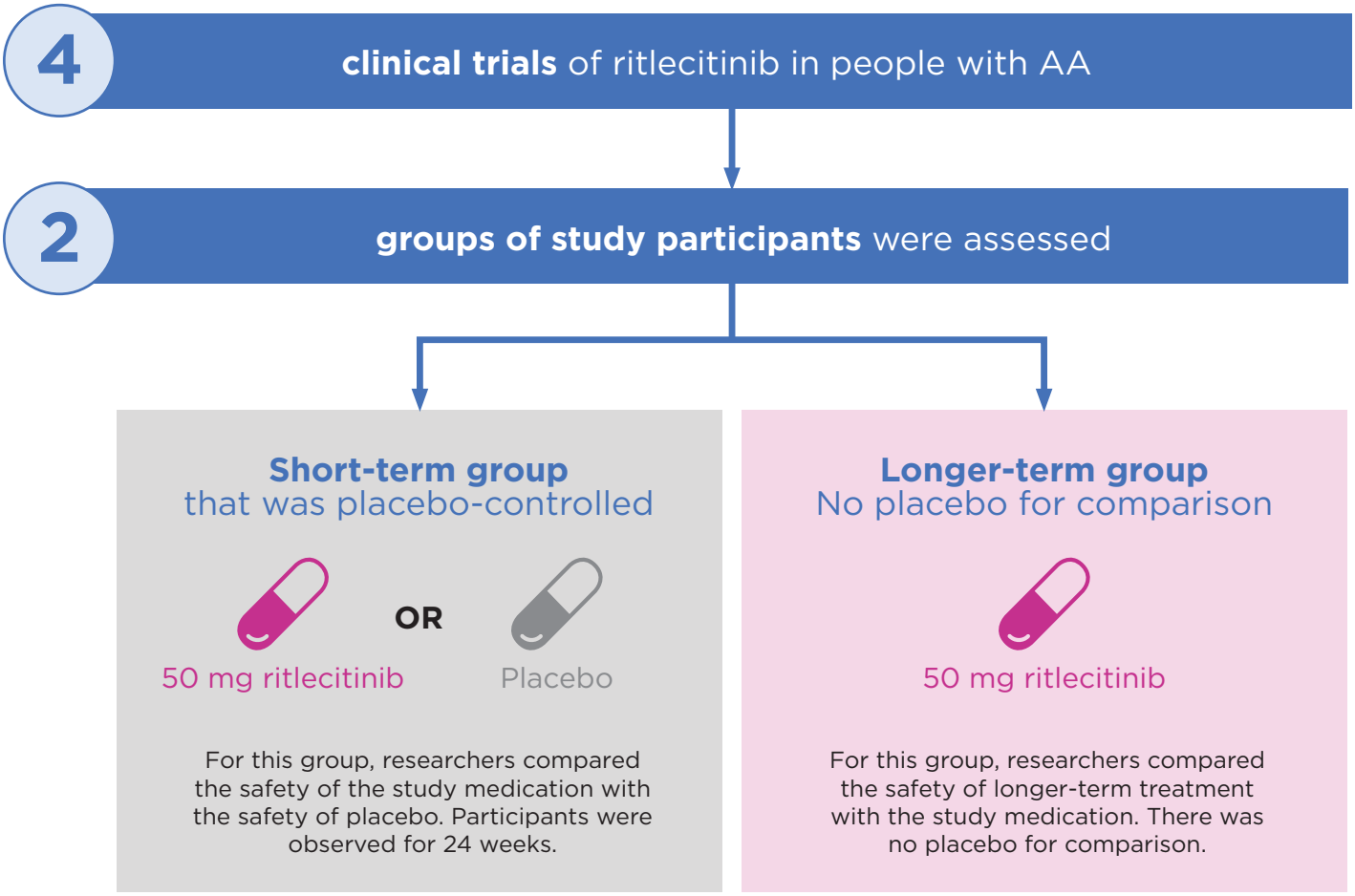
- Alopecia areata (or "AA" for short) is an autoimmune disease which causes a person to lose their hair.
- Hair loss can range from small patches of hair loss to complete loss of scalp, face, and/or body hair.
- AA affects 2% of people (2 out of 100 people) around the world. It can affect adults and children of all ages, races, and sexes.
- Hair loss caused by AA can lead to other problems such as social fear or worry and poor quality of life.

WHAT IS RITLECITINIB?

- Ritlecitinib is a medicine that blocks processes that are known to play a role in causing hair loss in people with AA.
- Ritlecitinib is taken by mouth as a pill once a day.
- Ritlecitinib is approved to treat people aged 12 years and older with severe AA.
- The dose that is approved is 50 mg taken once a day.

WHAT DID THIS STUDY LOOK AT?

- Many different clinical trials have studied the safety and effectiveness of ritlecitinib in people with AA.
- This study combines the safety information from 4 of these clinical trials.
- Participants in these trials were given different doses of ritlecitinib. This summary shows results for the 50 mg group.
- Some participants in the 50 mg group were given 200 mg ritlecitinib once a day for 4 weeks before starting 50 mg once a day. The results from these participants were combined with those from participants who were given 50 mg ritlecitinib once a day.



Any new health problems that were reported by study participants after they started taking medicine were recorded by the researchers. These are called **adverse events**. Adverse events may or may not be caused by the study medication.

WHO TOOK PART IN THIS STUDY?

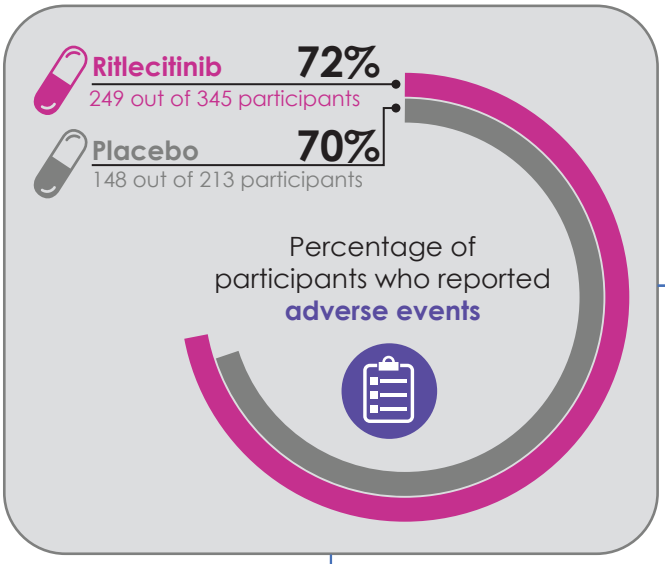
- People aged 12 years or older who had been diagnosed with AA participated in the studies.
- People in this study had lost a quarter or more of hair from their scalp. On average, most people who took part had lost over 80% of hair from their scalp.

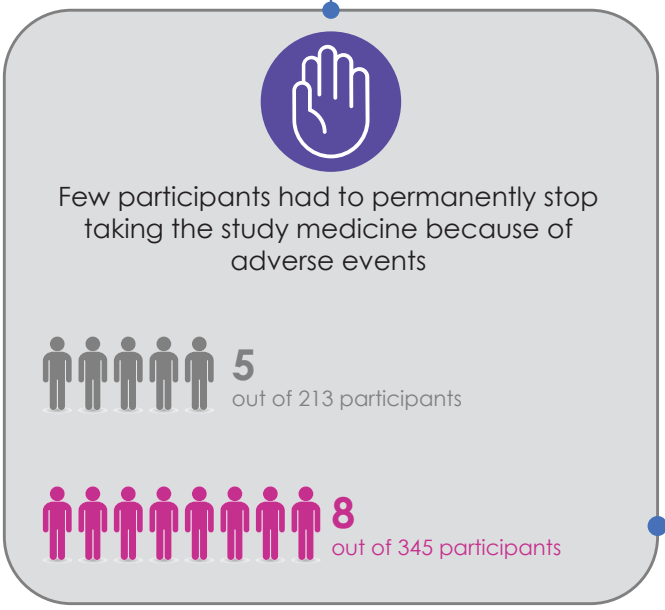
	Short-term group (placebo-controlled)	**Longer-term group** (no placebo comparator)
	 Ritlecitinib **or**  Placebo	 50 mg ritlecitinib
	881 people 50 mg ritlecitnib: 345 people Placebo: 213 people	1228 people
	34.2 years old	33.8 years old
	64% female 560 out of 881 people	64% female 780 out of 1228 people
	Treated for a median of 169 days	Treated for a median of 547 days

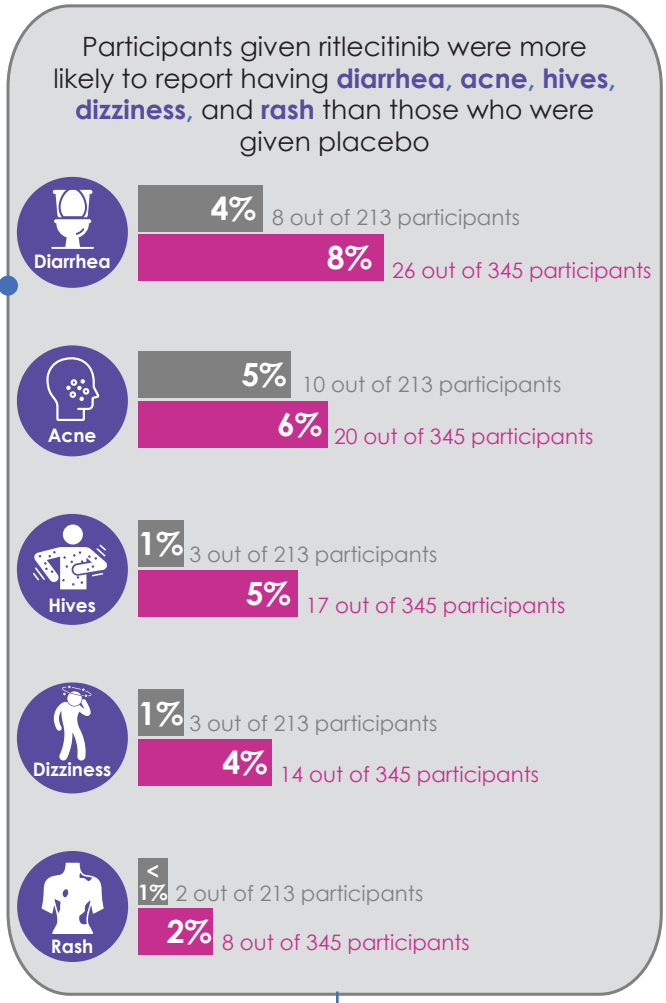
WHAT WERE THE RESULTS OF THIS STUDY?

Short-term group

- On average, people in this group took ritlecitinib or placebo for 163 days (which is just over 5 months).
- People who were given ritlecitinib were more likely to report diarrhea, acne, hives, dizziness, and rash than people who were given placebo.







These adverse events were **generally mild or moderate** and did not mean the participant had to stop taking the study medicine permanently

Longer-term group

- On average, people in this group took ritlecitinib for 540 days or more (which is the same as 18 months or more).
- This means that some participants took ritlecitinib for longer than this. At the time of these results, some participants had been taking ritlecitinib for around 3 years.
- This allowed researchers to look at adverse events that do not happen very often. Some adverse events, including cancers and problems with the cardiovascular system, may only appear after a person has been taking a medicine for a long time.

Adverse events of interest in participants who took 50 mg ritlecitinib

Herpes zoster (also known as shingles)
18 out of 1228 participants (1.5%) had herpes zoster.
Most of these events were mild or moderate and all participants recovered.

Serious infections (including COVID-19)
12 out of 1228 participants (1%) had serious infections.
All participants recovered.

Cancer
7 out of 1228 participants (less than 1%) had cancer.
4 of these were breast cancer.
1 of these participants died from breast cancer.

Heart problems
3 out of 1228 participants (less than 1%) had heart problems.
1 of these participants died.

Blood clots in the veins
1 out of 1228 participants (less than 1%) had a blood clot in the lungs (this is called a pulmonary embolism).

- A small number of participants had cancer or heart problems or blood clots in this study. Some of these participants also had risk factors which may have put them at higher risk.
- This means it is not always clear if these events were related to ritlecitinib treatment or not, and so longer studies are needed.

Research also looked at changes to **different blood cells**:

- There were small changes to some blood cells after 4 weeks of ritlecitinib treatment, but levels generally stayed the same throughout treatment.
- Some people have experienced a decrease in the number of white blood cells. A very small number of people (2 out of 1228) had to stop taking the study medication and leave the study all together because they had low levels of white blood cells which can increase the risk of infection.

WHAT ARE THE MAIN CONCLUSIONS OF THIS STUDY?

- This analysis looked at the longer-term safety of ritlecitinib for the treatment of AA.
- Most adverse events were mild and manageable and did not mean that people had to stop taking ritlecitinib.
- The study is still happening– researchers will continue to look at how safe ritlecitinib is in people with AA who take it for up to 5 years.
- Overall, ritlecitinib was found to have an acceptable safety profile in patients aged 12 years and older who have been diagnosed with AA.

WHO IS THIS ARTICLE FOR?

This summary is by the authors of the original article to help patients with AA, caregivers, patient advocates, and healthcare professionals understand the results of the ALLEGRO clinical trials.

WHERE CAN READERS FIND MORE INFORMATION ON THIS STUDY?

The original article "Integrated safety analysis of ritlecitinib, an oral JAK3/TEC family kinase inhibitor, for the treatment of alopecia areata from the ALLEGRO clinical trial program" was published in the *American Journal of Clinical Dermatology* (2024).
You can read the full article at
https://doi.org/10.1007/s40257-024-00846-3

The 4 clinical trials used in this study are

NCT02974868 | NCT04517864 | NCT03732807 | NCT04006457

For more information on clinical studies in general, please visit:
https://www.clinicaltrials.gov/ct2/about-studies/learn

For more information about alopecia areata, please visit
https://www.pfizer.com/disease-and-conditions/alopecia-areata

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