Plain Language Media Summary

NOVARTIS

Secukinumab as a treatment for psoriatic arthritis predominantly affecting the joints of the back and neck (axial joints)

Full abstract title: Secukinumab provides sustained improvements in clinical and imaging outcomes in patients with psoriatic arthritis and axial manifestations: Results from the MAXIMISE trial

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Please note that this summary only contains information from the full ACR 2020 scientific abstract and selected supporting references. The results of this study may not reflect those of other studies. This summary is not intended to provide medical advice.

Why was this study done?

To explore whether secukinumab can treat a type of psoriatic arthritis (PsA) that predominantly affects the back and neck.

PsA is a type of inflammatory arthritis that occurs in some patients with psoriasis. Inflammation is one way the body fights infection, but it can also become a problem if it occurs more than needed or happens without a good reason. Research suggests continued inflammation from PsA can result in joint damage later on.[1]

In PsA, inflammation results in swollen and painful joints and tendons, and can happen in any area of the body.[1] An effective treatment may be able to peristently dampen down inflammation to relieve this swelling and pain, and reduce the risk of joint damage occurring later on.

PsA can affect the back and neck, which are known as the axial joints. Axial disease is thought to affect 25-70% of patients with PsA, which may add up to 35 million people worldwide.[2,3]

The symptoms of PsA with axial disease include:[3,4]

- **pain in the joints and back**
- **fatigue**
- **stiffness in the morning**
- **impaired physical function affecting work and other activities**
- **problems with self-care**
- **feelings of anxiety/depression**

Secukinumab is a type of medication called a biologic. It helps reduce inflammation by blocking one of the proteins that activates inflammatory cells.[5]

What did this study look at?

The study looked at improvement in the severity of axial manifestations in patients with PsA after being treated with secukinumab for 12 weeks (3 months) and up to 52 weeks (1 year).

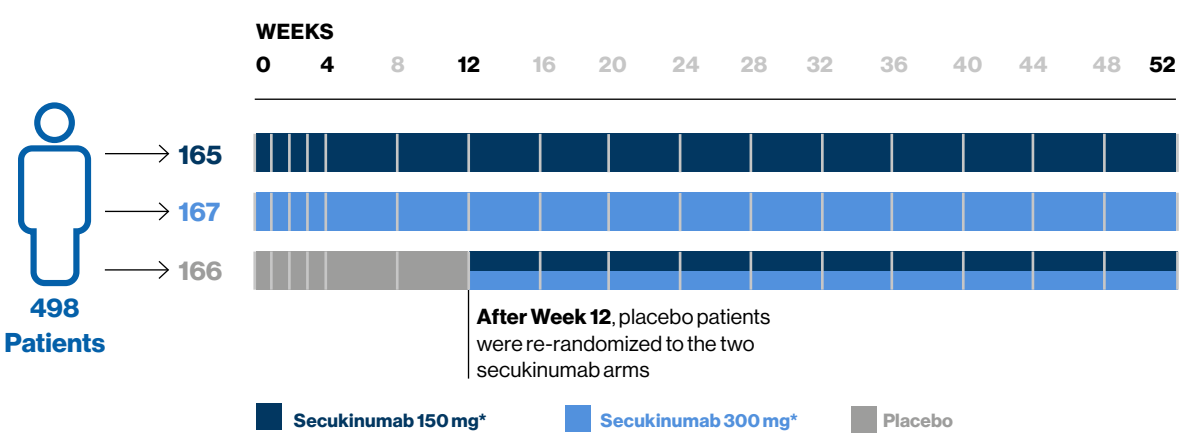
Improvement was measured using different methods. One of these is the Assessment in Ankylosing Spondylitis (ASAS) response criteria, which is a scale of symptoms including how the inflammation of the axial joints affects the patient's life, ability to do things (function) and pain. The study looked at how many patients had a 20% improvement in their symptoms. This is abbreviated as ASAS20, with measurements taken at the start, 1 month, 3 months and at 1 year. Patients were also asked to assess how much pain they had in their spine using a scale that allows you to give a score from 0 (no pain) to 100 (as bad as it could be).

In addition, the study looked at what was happening to the inflammation of the spine using a scanning technique called magnetic resonance imaging (MRI).

To check if any improvement was the result of treatment with secukinumab, the proportion of patients with an ASAS20 response after taking secukinumab was compared with the proportion of patients with an ASAS20 response that were given an injection containing no treatment (a placebo). After 12 weeks of no treatment, those in the placebo group could then receive secukinumab treatment.

The patients in this study had previously tried to relieve their symptoms with at least two anti-inflammatory pain medications but were still experiencing a pain score of more than 40 on the 0-100 pain scale.

Design of the study

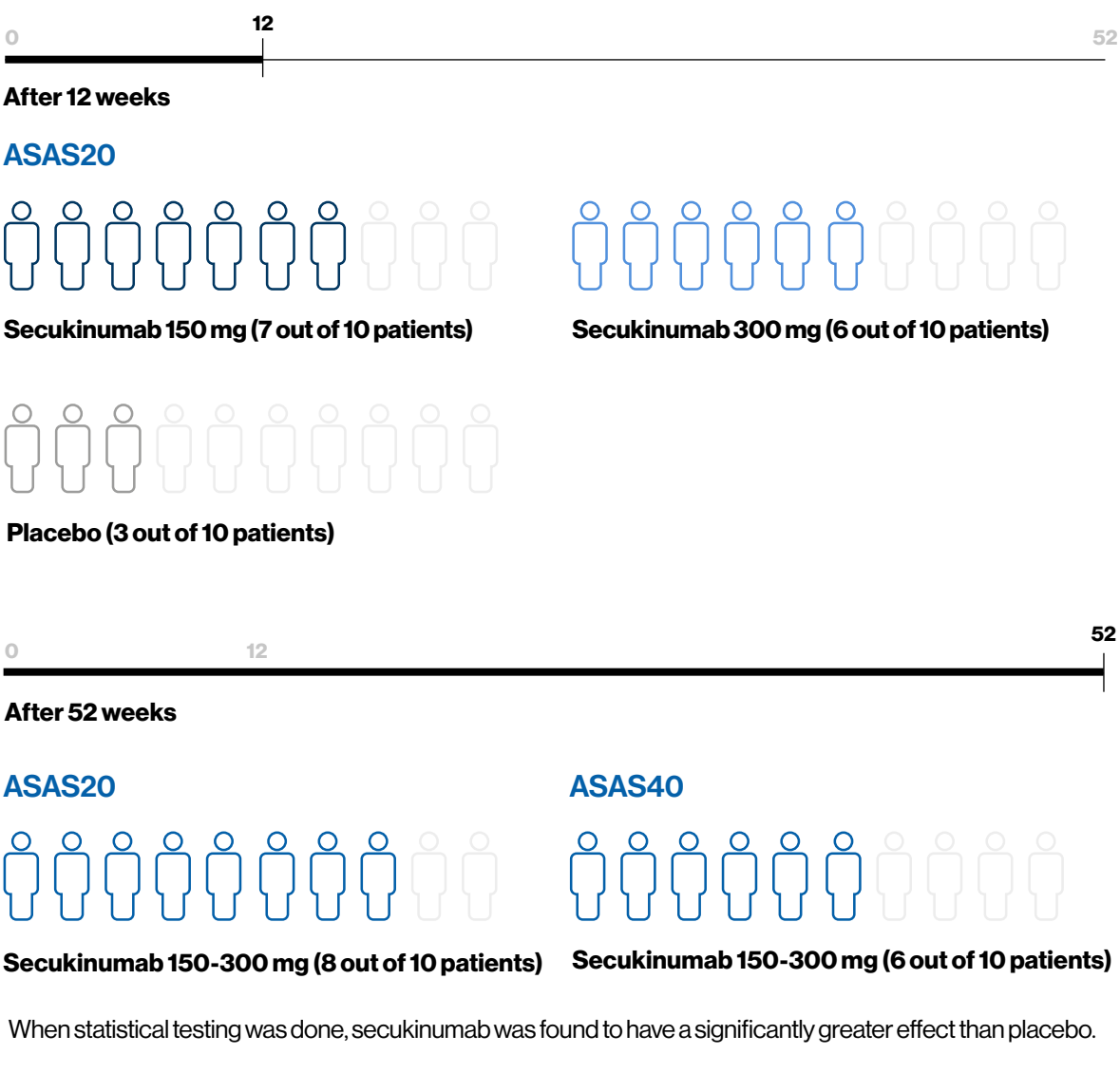


Vertical gray lines show when patients received an injection of treatment during the study.

**Secukinumab 150 mg and 300 mg every 4 weeks are the approved regimens to treat PsA*

What did this study find?

Number of people achieving ASAS20 at Week 12 and ASAS20 and ASAS40 at Week 52



When statistical testing was done, secukinumab was found to have a significantly greater effect than placebo.

Pain severity at 52 weeks

This shows the average reduction in back and neck pain from the start of the study on a 0-100 scale.

Inflammation on MRI

At 52 weeks, patients who had received secukinumab treatment showed a reduction in inflammation at the axial skeleton (including the entire spine) on an MRI scan.

Safety

The safety of secukinumab was consistent with previous studies in psoriasis and PsA.

Why does this matter?

This study showed that secukinumab provided long-term improvement in patients with the axial form of PsA and back pain.

Patients who began treatment after 3 months of placebo caught up to those who were treated with secukinumab from the start of the study, with similar improvements seen in inflammation a year after the initiation of the study. Stronger results were seen in patients switching to secukinumab 300 mg versus 150 mg.

To date, there have been limited studies investigating biologic use in these patients. This study provides additional information about lasting treatments that could help doctors determine treatment choices.[3]

Glossary

ASAS20 (Assessment in SpondyloArthritis 20%) response:
a ≥20% improvement in three out of four areas of a scoring system designed to rate the severity of inflammation in axial joints in PsA. It includes how the inflammation of the axial joints affects the patient's life, ability to do things (function) and pain.

ASAS40 (Assessment in SpondyloArthritis 40%) response:
a ≥40% improvement in three out of four areas of a scoring system designed to rate the severity of inflammation in axial joints in PsA. It includes how the inflammation of the axial joints affects the patient's life, ability to do things (function) and pain.

Axial
[ax-eel]:
affecting the back, ribcage, head and neck.

Biologic:
a treatment made using living organisms, rather than being chemically synthesized.

Inflammation:
the body's immune response to an irritant, which involves a variety of cells that release different substances to help the body fight the infection. In some diseases, the immune cells can attack the body by mistake – this is known as an autoimmune disease.

Psoriatic arthritis
[saw-ree-at-ik ahr-thry-tis]:
a form of joint inflammation that affects some people who have psoriasis – a condition that features red patches of skin topped with silvery scales.

Significant(ly):
statistically, the difference between the groups is unlikely to have occurred by chance. This difference is therefore likely to be related to the treatment given to the patients.

Who sponsored this study?

Novartis Pharma AG, Basel, Switzerland sponsored both this study and the writing of this plain language media summary.

Further information

More on the MAXIMISE study can be found here: https://clinicaltrials.gov/ct2/show/NCT02721966

References

1. American College of Rheumatology. Psoriatic Arthritis. Available from: https://www.rheumatology.org/I-Am-A/Patient-Caregiver/Diseases-Conditions/Psoriatic-Arthritis [Last accessed: November 2020].
2. Feld J, et al. Rheum Rev. 2018;14(6):363-371.
3. McInnes IB, et al. Lancet. 2015;386(9999):1137-1146.
4. Mease PJ, et al. J Rheumatol. 2018;45(10):1389-1396.
5. Blair HA. Drugs. 2019;79(4):433-443.