Plain Language Media Summary

NOVARTIS

The effect of secukinumab on non-radiographic axial spondyloarthritis at 2 years

Full abstract title: Secukinumab 150 mg Provides Sustained Improvement in Signs and Symptoms of Non-radiographic Axial Spondyloarthritis: 2-year Results from the PREVENT Study

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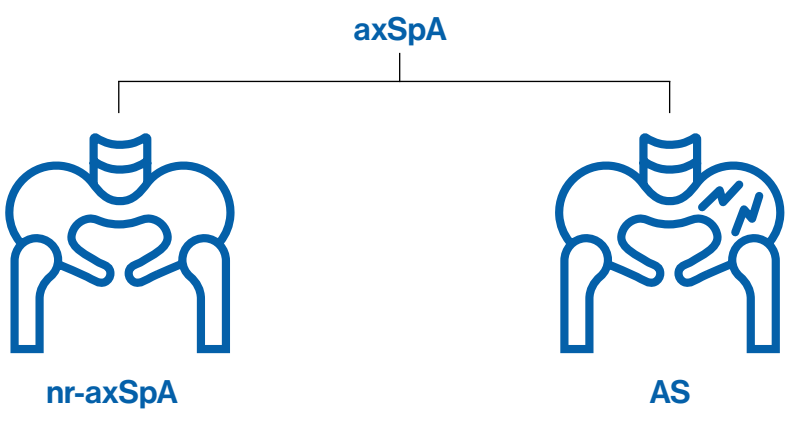
Please note that this summary only contains information from the full EULAR 2021 scientific abstract and selected supporting references. The results of this study may not reflect those of other studies. This summary is not intended to provide medical advice.

Why was this study done?

To investigate the effect of secukinumab on the symptoms of non-radiographic axial spondyloarthritis through 2 years of treatment.

Non-radiographic axial spondyloarthritis (nr-axSpA) is part of a group of long-term diseases called axial spondyloarthritis (axSpA).[1] In axSpA, the body's immune system is overactive, causing inflammation around the spine and pelvis, leading to back pain. Inflammation can be good (eg, in fighting infection), but it can also become a problem if it occurs more than needed or without a good reason.

The axSpA spectrum includes ankylosing spondylitis (AS), where joint damage is generally visible on X-ray, and nr-axSpA, where joint damage is not visible on X-ray.[2]



Secukinumab helps reduce inflammation by blocking one of the chemicals that activates inflammatory cells.[3] Therefore, it could help relieve some nr-axSpA symptoms. Secukinumab has previously been shown to significantly improve the signs and symptoms of patients with nr-axSpA in this study through Week 52.[4]

The symptoms of nr-axSpA and AS are comparable and include:[5]

- **spinal pain**
- **pain in the joints and back**
- **fatigue**
- **stiffness in the morning**
- **difficulty functioning in daily life**

If left untreated, these symptoms can affect people's daily lives, and may limit their ability to participate in normal activities such as getting themselves ready in the morning, working and enjoying time with family.[5]

There are approximately 3.5 million patients with axSpA (1.7 million with nr-axSpA) in the top five European countries and US.[2] The prevalence of axSpA in adults is similar to that of rheumatoid arthritis.[6]

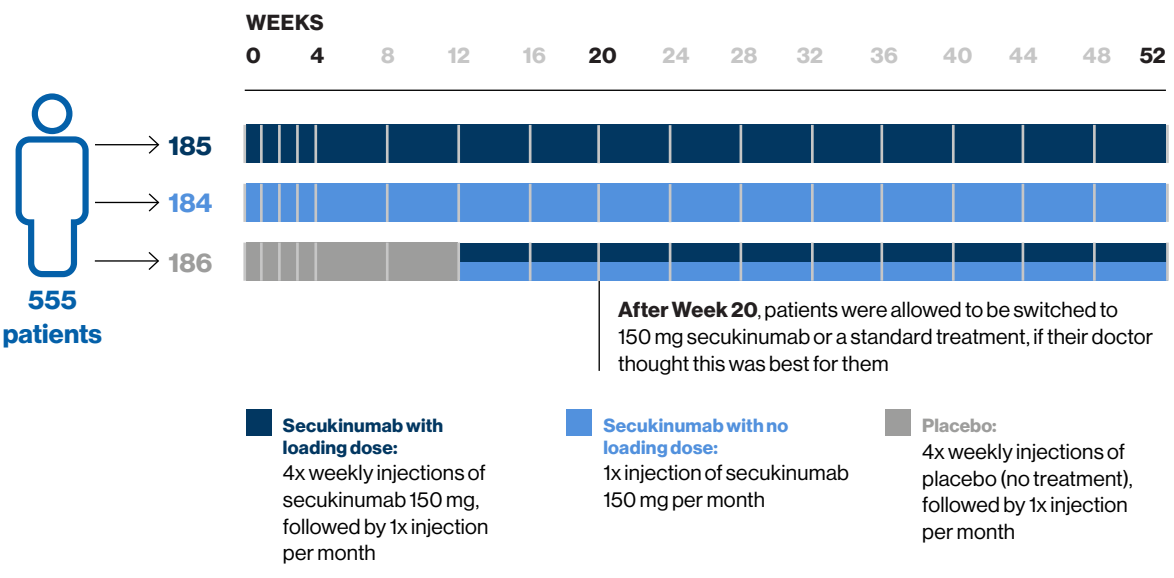
What did this study look at?

The study looked at how many nr-axSpA patients had a 40% improvement in the severity of their disease after being treated with secukinumab for 52 weeks (one year) and 104 weeks (two years).

Improvement was measured using the Assessment in Ankylosing Spondylitis response criteria (ASAS), which is a scale of symptoms that assesses how the disease generally affects the patient's life, pain, ability to do things (function) and inflammation. As the study looked at how many patients had a 40% improvement in their symptoms, this is abbreviated to ASAS40.

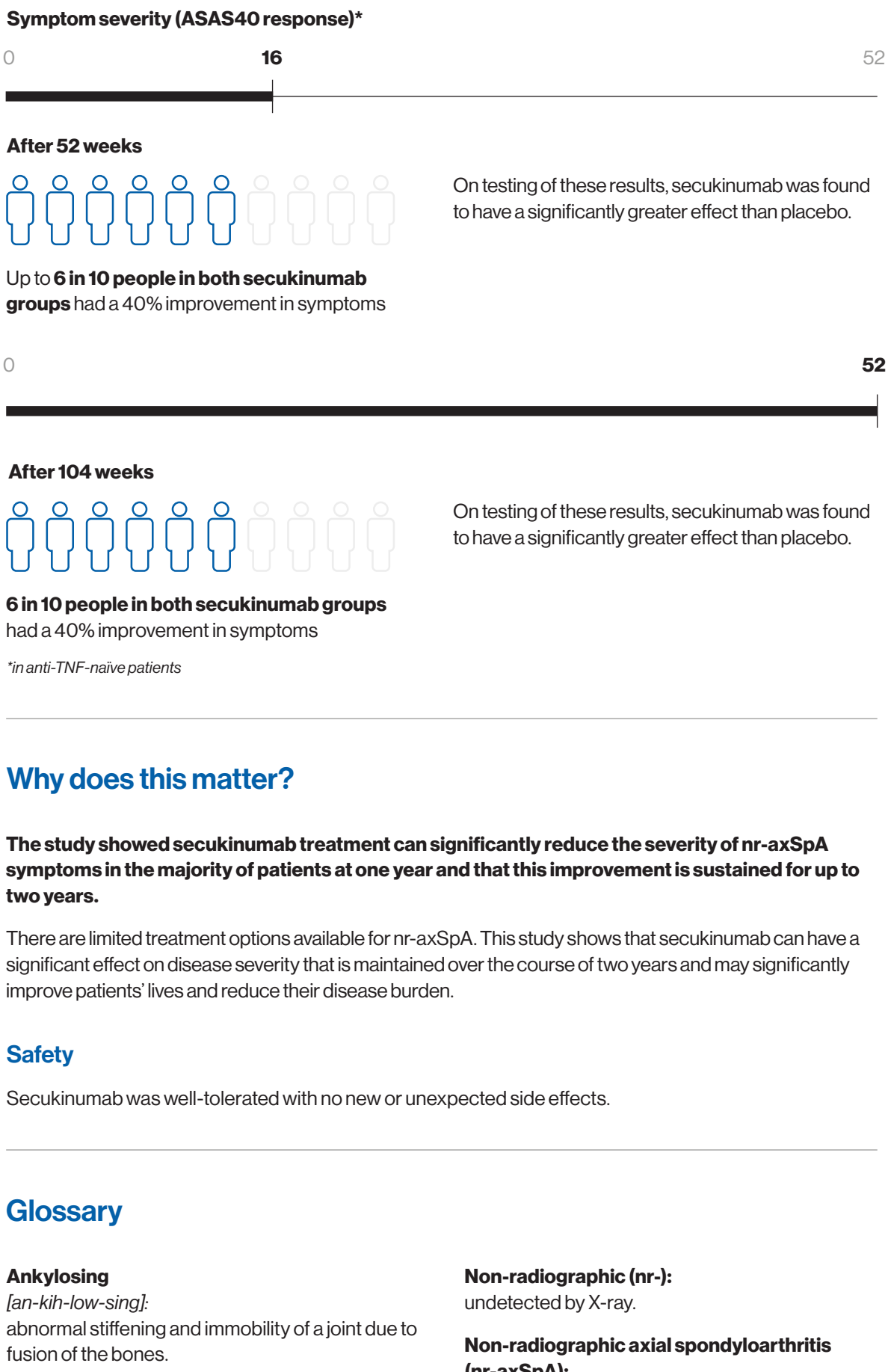
Secukinumab is administered through injections. Frequent injections at the start of treatment are called a loading dose. If a loading dose is not required for secukinumab to work in nr-axSpA patients, the burden of frequent initial injections could be avoided.

Design of the study



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

What did this study find?



Why does this matter?

The study showed secukinumab treatment can significantly reduce the severity of nr-axSpA symptoms in the majority of patients at one year and that this improvement is sustained for up to two years.

There are limited treatment options available for nr-axSpA. This study shows that secukinumab can have a significant effect on disease severity that is maintained over the course of two years and may significantly improve patients' lives and reduce their disease burden.

Safety

Secukinumab was well-tolerated with no new or unexpected side effects.

Glossary

Ankylosing
[an-kih-low-sing]:
abnormal stiffening and immobility of a joint due to fusion of the bones.

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 spondyloarthritis (axSpA)
[ax-eel spon-dill-lo-ar-thri-tiss]:
a painful, chronic (long term) inflammatory disease that primarily affects the spine and sacroiliac (where the spine joins the pelvis) joints.

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

Non-radiographic (nr-):
undetected by X-ray.

Non-radiographic axial spondyloarthritis (nr-axSpA):
arthritis of the spine that is not detected by X-ray.

Placebo:
a substance with no active component which has no therapeutic effect.

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 medication given to the patients.

Spondylitis
[spon-dill-eye-tiss]:
inflammation of the spine or vertebrae.

Who sponsored this study?

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

Further information

More on the PREVENT study can be found here: https://onlinelibrary.wiley.com/doi/full/10.1002/art.41477

References

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3. Blair HA. *Drugs*. 2019;79(4):433-443.
4. Deodhar A, et al. *Arthritis Rheumatol*. 2021;73(1):110-120
5. Mease PJ, et al. *Arthritis Care Res (Hoboken)*. 2018;70(11):1661-1670.
6. Axial Spondyloarthritis International Federation. About ASIF. Available from: https://asif.info/about/ [Last accessed: June 2021].