

BEISPIELSTUDIE

A comparison of the efficacy of secukinumab and ustekinumab in patients with plaque-type psoriasis: a randomized-controlled trial.

KATEGORISIERUNG

Gattung

Forschungsprojekt mit lebenden Personen

Art

Unterart

Klinischer Versuch mit Arzneimitteln (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g MepV)

BACKGROUND

This study compared the efficacy of secukinumab to ustekinumab (Stelara®) in patients that have plaque-type psoriasis.

METHODS

Adults, aged 18 or older, who suffered from moderate to severe plaque type psoriasis for at least 6 months before randomization, were randomly allocated to receive secukinumab 300 mg once every weeks (at weeks 0, 1, 2, 3), followed by monthly dosing starting at week 4 and continuing through week 48, or to receive ustekinumab (Stelara®) 45mg once a week (at weeks 0, 4, 8 and 12). Severity and extent of psoriasis was measured using the PASI score (Psoriasis Area and Severity Index). Primary outcome was the difference in the proportion of PASI 90 responders after 16 weeks.

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?

Ja

BECAUSE

This project was based on a study protocol that defines the exact procedures to be used. It included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Adults ("persons") aged 18 or older, who suffered from moderate to severe plaque type psoriasis for at least 6 months before randomization ("research concerning human diseases") were randomly allocated to receive secukinumab or ustekinumab (Stelara®).

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?

Ja

BECAUSE

Adults ("persons") aged 18 years or older, who suffered from moderate to severe plaque type psoriasis for at least 6 months before randomization, were included in this study.

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?

Ja

BECAUSE

Adults ("persons") who suffered from moderate to severe plaque type psoriasis for at least 6 months before randomization were randomly allocated ("prospectively assigned") to receive secukinumab or ustekinumab (Stelara®) ("health-related intervention [therapeutic measure]"). The research project compared the proportion of PASI 90 responders after 16 weeks ("to investigate its effect on health").

Wird in der Studie ein Arzneimittel (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g Medizinprodukteverordnung (MepV) vom 1. Juli 2020) untersucht?

Ja

BECAUSE

The effects of secukinumab and ustekinumab (Stelara®) were investigated ("medicinal products") in this clinical trial.

Wird in der Studie ein Medizinprodukt (In-vitro-Diagnostika ausgenommen) oder ein anderes Produkt nach Artikel 1 der Medizinprodukteverordnung (MepV) (Stand am 26. Mai 2022) untersucht?

Nein

BECAUSE

Wird in der Studie eine Intervention untersucht, die weder ein Heilmittel oder ein Transplantatprodukt, noch ein Produkt nach Art. 2a Abs. 2 Heilmittelgesetz (HMG) (Stand ab 26. Mai 2021) oder eine Transplantation ist?

Nein

BECAUSE

Wird in der Studie eine Gentherapie oder ein pathogener Organismus untersucht?

Nein

BECAUSE

Ist das Arzneimittel in der Schweiz zugelassen?

Nein

BECAUSE

The effects of secukinumab and ustekinumab (Stelara®) were investigated in this clinical trial. Ustekinumab (Stelara®) is "authorised" for the Swiss market (approval number Stelara®: 61267 [Swissmedic]). However, secukinumab does not have a marketing authorisation in Switzerland.