kofam

Koordinationsstelle Forschung am Menschen

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.

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**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").

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**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.

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**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**

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**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**

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

**BECAUSE**

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**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.

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