kofam

Koordinationsstelle Forschung am Menschen

CASE STUDY

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

CATEGORISING

Kind
Research project involving living people

Type
Clinical trial

Subtype
Clinical trial with medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g MedDO)

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.

QUESTIONS OF THE CATEGORISER

Does the research project come under the scope of application of the Human Research Act?
Yes

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®).

Is the research project a project involving living persons?
Yes

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.

Is the research project a clinical trial?
Yes

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").

Does the trial involve investigating medicinal products (including combinations according to Art. 2 Para. 1 Letters f and g Medical Device Ordinance (MedDO) from the July 1, 2020)?
Yes

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

Does the trial involve investigating a medical device (in vitro diagnostics excluded) or any other device as defined in Article 1 of the Medical Devices Ordinance of July 1, 2020?
No

BECAUSE

Does the trial investigate an intervention that is neither a therapeutic product nor a transplant product, nor a product according to Art. 2a para. 2 Therapeutic Products Act (TPA) (Status from May 26, 2021), nor a transplant?
No

BECAUSE

Does the trial investigate a transplant product?
No

BECAUSE

Does the trial investigate gene therapy or a pathogenic organism?
No

BECAUSE

Is the IMP authorised in Switzerland?
No

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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todo