BEISPIELSTUDIE

Prospective Evaluation of Etravirine for HIV-infected Patients in Need of Lipid-lowering Drugs

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

Dyslipidaemia, characterized by raised triglyceride and low-density lipoprotein cholesterol and reduced high-density lipoprotein cholesterol levels, is common in HIV-infected individuals. Dyslipidaemia has been associated with HIV infection and antiretroviral therapy. This study evaluated the frequency with which the replacement of Lopinavir/Ritonavir, Atazanavir/Nitonavir, Darunavir/Ritonavir or Efavirenz by Etravirin (Intelence®) in dyslipidemic patients with suppressed viremia made it unnecessary to administer statins.

METHODS

The study included HIV-infected patients, aged 18-70 years, on statin treatment for at least 3 months, and on a stable (> 3 months) antiretroviral therapy treatment that included at least one of the following drugs: Lopinavir/Ritonavir, Atazanavir/Nitonavir, Darunavir/Ritonavir or Efavirenz. Statin treatment of dyslipidemic HIV patients on antiretroviral drugs was interrupted during 4 weeks. At week 4, patients who qualified for a lipid lowering drug (calculated LDL-C≥ 3mmol/L) replaced lopinavir/ritonavir, atazanavir/ritonavir, darunavir/ritonavir or efavirenz with Etravirine (Intelence®), 400 mg/day, once daily. The primary outcome was the proportion of patients that no longer qualified for statin treatment at 12 weeks (after 8 weeks of Etravirine treatment).

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). Participants were HIV-infected adults ("persons") on statin treatment for at least 3 months, and on a stable antiretroviral therapy treatment that included at least one of the following drugs: Lopinavir/Ritonavir, Atazanavir/Nitonavir, Darunavir/Ritonavir or Efavirenz. Statin treatment was interrupted for 4 weeks. At week 4, patients who qualified for a lipid lowering drug replaced their antiretroviral treatment with Etravirine, 400 mg/day once daily ("research concerning human diseases").

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

BECAUSE
HIV-infected adults ("persons") were included in this research project if they were on statin (Simcora® 20/40/60/80) treatment for at least 3 months, and on stable antiretroviral therapy treatment.

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

BECAUSE
The investigator asked HIV infected adults on statin treatment for at least 3 months, and on a stable antiretroviral therapy treatment, to interrupt their statin treatment for 4 weeks. At week 4, patients who qualified for a lipid lowering drug replaced their antiretroviral treatment with Etravirine (Intelence®), 400 mg/day, once daily ("prospectively assigned"). The study assessed the proportion of patients who no longer qualified for statin treatment after 8 weeks of Etravirine (Intelence®) treatment ("to investigate its effects on health or on the structure and function of the human body").

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
This study investigated the effects of interrupting statin and replaced antiretroviral treatment with Etravirine (Intelence®). 400 mg/day once daily in dyslipidemic HIV-infected patients ("medicinal products").

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?
Ja

BECAUSE
The interruption of statins (Simcora®) is not considered a pharmaceutical intervention.

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

BECAUSE

Ist das Arzneimittel in der Schweiz zugelassen?
Ja

BECAUSE
This study investigated the effects on HIV-infected patients of interrupting statin (Simcora®) and replaced antiretroviral treatment with Etravirine (Intelence®), 400 mg/day, once daily. Etravirine (Intelence®) is "authorised" for the Swiss market (approval numbers for Etravirin (Intelence®) 58483 (Swissmedic).

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Wird in der Studie ein Placebo verwendet oder wird der Originalzustand des verwendeten Arzneimittels oder seine Verpackung verändert?
Nein

BECAUSE
This study investigated the effects on HIV-infected patients of interrupting statin (Simcora®) and replaced antiretroviral treatment with Etravirine (Intelence®), 400 mg/day, once daily. Etravirine (Intelence®) is "authorised" for the Swiss market and was provided "as is", unchanged.

Wird das Arzneimittel in der Studie gemäss Fachinformation angewendet?
Ja

BECAUSE
This clinical trial investigated the effects on HIV-infected patients of interruption of interrupting statin and replaced antiretroviral treatment with Etravirine (Intelence®), 400 mg/day, once daily. Etravirin (Intelence®) is approved to treat HIV-infected persons (antiretroviral treatment). According to the summary of product characteristics, the maximum recommended dose for Etravirin (Intelence®) is 200mg, twice a day. The indication (HIV-infected patients) and dosage does not deviate from the approved standard.

Ist die Intervention mit höchstens minimalen Risiken und Belastungen für die Teilnehmenden verbunden?
Ja

BECAUSE
This clinical trial investigated the effects of interrupting statin (Simcora®) and replaced antiretroviral treatment with Etravirine (Intelence®), 400 mg/day, once daily, on dyslipidemic HIV-infected patients. The goal of the study was to assess the proportion of patients who no longer qualified for statin (Simcora®) treatment after 8 weeks of treatment with Etravirine (Intelence®). The interruption of statin involves only minimal risk for the participants.

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