

## 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 Etravirine (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 $\geq$  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 (Simcor® 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).

**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. Etravirine (Intelence®) is approved to treat HIV-infected persons (antiretroviral treatment). According to the summary of product characteristics, the maximum recommended dose for Etravirine (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.