CASE STUDY

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

CATEGORISING

Type:
Clinical trial

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

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 ≥ 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).

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). 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").

Is the research project a project involving living persons?

Yes

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.
Is the research project a clinical trial?
Yes

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 (Inte酚el®), 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 (Inte酚el®) treatment (“to investigate its effects on health or on the structure and function of the human body”).

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

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?
Yes

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

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?
Yes

BECAUSE
This study investigated the effects on HIV-infected patients of interrupting statin (Simcora®) and replaced antiretroviral treatment with Etravirine (Inte酚el®), 400 mg/day, once daily. Etravirine (Inte酚el®) is “authorised” for the Swiss market (approval numbers for Etravirin (Inte酚el®) 58483 (Swissmedic).
**Does the IMP administration comply with the specifications in the summary of product characteristics (SPC)?**

Yes

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

**Does the intervention involve minimal risks and stress for the participating persons?**

Yes

BECAUSE
This clinical trial investigated the effects of interrupting statin (Simcora®) and replaced antiretroviral treatment with Etravirine (Intencelence®), 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 (Intencelence®). The interruption of statin involves only minimal risk for the participants.

**Is a placebo used in the trial, or is the original status of the medicinal product or its packaging as approved by Swissmedic modified?**

No

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