kofam

Koordinationsstelle Forschung am Menschen

CASE STUDY

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

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

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).

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 (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").

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 (Intelence®). 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 (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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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 (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.

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 (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.

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 (Intelence®), 400 mg/day, once daily. Etravirine (Intelence®) is "authorised" for the Swiss market and was provided "as is", unchanged.
