kofam

Koordinationsstelle Forschung am Menschen

CASE STUDY

Optimal duration of dual antiplatelet therapy after coronary stent implantation

CATEGORISING

Kind
Research project involving living people

Type
Clinical trial

Subtype
Clinical trials with interventions that are neither a therapeutic product nor a transplant product, nor a transplant ("other clinical trial")

BACKGROUND

Patients receiving a coronary stent during a percutaneous corornary intervention need to take dual antiplatelet therapy after the procedure. The aim of the antiplatelet therapy is to prevent patients from stent-related blood clots and other major adverse cardiovascular events following the implantation. Dual antiplatelet therapy consists of regular intake of oral aspirin and a second anti clotting drug. The aim of the study was to evaulate the optimal duration of such a dual antiplatelet therapy.

METHODS

Patients undergoing stent placement for the treatment of coronary artery lesions were randomized to receive a prescription for clopidogrel for 12 months or 24 months. In addition, all patients received a prescription for aspirin life-long. Patients were responsible to obtain the prescribed treatment with the prescription at their local pharmacy. Randomized prescriptions specified the International Nonproprietary Name (INN) and therefore left the descision on which specific preparation (proprietary medicinal product) to be handed to the patient at the discretion of the pharmacist. Patients were assessed every 6 months. Patients in the 12-month arm were reminded to stop treatment of clopidogrel at the 12-month visit and patients in the 24-month arm at the 24-month visit. Patients were followed-up for 5 years. The trial had two primary outcomes: 1) the composite of all-cause death and major cardiovasular events at 24-month follow-up; 2) major bleeding events at 24-month follow-up.

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). Women and men ("persons"), who received a coronary stent for coronary artery lesions ("research concerning human diseases"), were treated with dual antiplatelet therapy for either 12 or 24 months.

Is the research project a project involving living persons?
Yes

BECAUSE
Women and men ("persons"), who received a coronary stent for coronary artery lesions, were included in this project.

Is the research project a clinical trial?
Yes

BECAUSE
The investigator randomly assigned ("prospectively assigned") women and men ("persons") who received a coronary stent for coronary artery lesions to receive either a prescription for 12 or 24 months of clopidogrel treatment, a "health-related intervention (therapeutic measure)", and compared rates of major cardiovascular and bleeding events between groups ("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)?
No

BECAUSE
Although the effects of different length of clopidogrel treatment are investigated ("medicinal products") in this clinical trial the allocation actually randomized prescriptions. Drugs were not provided by investigators. The choice of the specific preparation (proprietary medicinal product) was left at the discretion of the pharmacist and not documented. Therefore, the trial took a pragmatic, real-world approach and had no direct control on the actual preparation used.

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
Although the effects of different length of clopidogrel treatment are investigated ("medicinal products") in this clinical trial the allocation actually randomized prescriptions. Drugs were not provided by investigators. The choice of the specific preparation (proprietary medicinal product) was left at the discretion of the pharmacist and not documented. Therefore, the trial took a pragmatic, real-world approach and had no direct control on the actual preparation used.

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

BECAUSE
This randomized-controlled, open trial investigates the effects of different lengths of clopidogrel treatment. Clopidogrel is a drug and various proprietary medicinal products are "authorised" for the Swiss market (e.g. approval number for Plavix®: 54509 (Swissmedic)). It is reasonable to assume that pharmacies will only provide authorised products to the patients. All authorised clopidogrel preparations are approved for prevention of atherothrombotic events in patients who received a coronary stent. The recommended dosing schedule is corresponds to dosing schedule in the protocol. Length of treatment is not explicitly mentioned in the package insert but only mentioned as long-term.Therefore, indication and dosage of clopidogrel in this research project corresponds with the approved indication.
