CPC-032 CLOPIDOGREL FOR THE TREATMENT OF CHILDREN WITH A SYSTEMIC-TO-PULMONARY ARTERIAL SHUNT
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Background Clopidogrel is a thienopyridine drug that acts by binding selectively and irreversibly to the adenosine diphosphate P2Y12 receptor on platelets. Platelet aggregation is consequently inhibited. Clopidogrel is used to prevent ischemic events in patients at risk, when other drugs fail or are not tolerated. Paediatric use is not authorised because of limited information about efficacy and safety.

Purpose To illustrate our experience in the three-month use of clopidogrel in children with a systemic-to-pulmonary arterial shunt, prior to definitive surgical intervention.

Materials and Methods On February 2012 a temporary systemic-to-pulmonary arterial shunt was placed in a four-month-old patient, affected by Tetralogy of Fallot with hypoplasia of the infundibulum and pulmonary valve. We administered two antiaggregant drugs, ASA 18 mg and clopidogrel 0.2 mg/Kg once a day, because of the high risk of thrombotic closure of the shunt. We chose an extemporary preparation of type 5 capsules with lactose as a diluent.

Results We prepared capsules from 0.75 to 3.5 mg. For all patients we obtained authorization by the Ethics Committee and the parents’ informed consent. After surgery, the children were observed for 7–8 days depending on clinical follow up and complications. We checked the blood count and shunt patency with clinical observation, analysis and echocardiogram. After discharge, patients were first recalled 10–15 days later, then after 1–2 months to see the doctor, have an ECG, blood tests and echocardiogram. It was not necessary. No serious side effects were observed.

Conclusions Paediatric clopidogrel treatment is rapidly increasing. A wider number of cases, a comparison with other professional experience, and, most of all, controlled clinical trials, would be desirable.

No conflict of interest.

CPC-033 COMPARING EFFECTIVENESS OF FIRST-LINE DISEASE MODIFYING DRUGS IN RELAPSING-REMITTING MULTIPLE SCLEROSIS PATIENTS
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Background Immunomodulatory drugs represent the best therapeutic option in first-line treatment of relapsing-remitting multiple sclerosis (RRMS). This group includes glatiramer acetate (GA) and three formulations of Interferon β (IFNβ): subcutaneous IFNβ1a (scIFNβ1a), intramuscular IFNβ1a (imIFNβ1a) and subcutaneous IFNβ1b (scIFNβ1b). Several studies have reported similar efficacy among IFNβ and GA preparations, while other have concluded that some differences exist between them.

Purpose To compare the effectiveness of first-line disease modifying drugs (FL-DMD) in patients with RRMS.

CPC-034 COMPARISON OF EFFECTIVENESS AND SAFETY OF PRIMARY PROPHYLAXIS WITH BIOSIMILAR FILGRASTIM VS REFERENCE MEDICINAL PRODUCT IN PATIENTS TREATED WITH R-CHOP
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Background Prophylactic administration of filgrastim can reduce the risk of febrile neutropenia (FN) in oncological patients undergoing myelosuppressive chemotherapy.

According to approved guidance on biosimilar drugs, clinical comparability can be obtained from results extrapolated from other indications.

Due to this simplified pathway, concerns about safety and effectiveness in some clinical settings may remain.

Purpose To compare the effectiveness and safety of biosimilar filgrastim (B) with the reference medicinal product (RMP) in patients with haematological malignancies treated with the R-CHOP regimen and undergoing primary prophylaxis (PP) with filgrastim.

Materials and Methods A single-centre, retrospective and translational study was performed: from March 2010 to October 2010 (RMP) and March 2011 to February 2012 (B).

Main endpoints were incidence of FN (per patient and per cycle), time to absolute neutrophil count (ANC) recovery, incidence of NP in first cycle (1stCy), number of hospitalisations days related to FN. Other endpoints and patient-related risk factors for FN were evaluated.

Results The results seem to support equivalence of effectiveness between these drugs. We did not find any safety-related incidents. More patients are being included to increase the sample size and allow statistical significance. These results may further support the use of the more cost-efficient option.

No conflict of interest.