Conclusion A significant difference in PFS was observed compared to published clinical trials PALOMA-2 (PFS 24.8 months) and PALOMA-3 (PFS 11.2 months). Otherwise, palbociclib showed a similar safety profile. However, further studies are required to establish effectiveness in clinical practice as 19/29 patients are still receiving treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Palbociclib: EPAR-Summary for the public. EMA.
2. Pivotal studies PALOMA-2 and PALOMA-3.

No conflict of interest.

4CPS-131 RUXOLITINIB AS SALVAGE THERAPY IN PAEDIATRIC PATIENTS WITH STEROID-REFRACTORY GRAFT-VERSUS-HOST DISEASE

¹E Serramontany*, ¹B Renedo Miro, ¹M Oliveras Arenas, ¹MJ Carreras Soler, ²MI Benitez Carabante, ¹M Roch Santed, ¹MQ Gorgas Torner. ¹Vall d'Hebron University Hospital, Pharmacy Service, Barcelona, Spain; ²Vall d'Hebron University Hospital, Paediatric Oncohaematology, Barcelona, Spain

10.1136/ejhp-pharm-2019-eahpconf.280

Background Steroid-refractory graft-versus-host disease (GVHD) is a significant complication of allogeneic haematopoietic stem cell transplantation (HSCT) and a leading cause of morbidity and non-relapse mortality.

Adult clinical trials with ruxolitinib have demonstrated benefit in this population, but there are no paediatric reports describing this effectiveness.

Purpose Analyse effectiveness and safety of ruxolitinib in paediatric patients, with steroid-refractory GVHD.

Material and methods Retrospective study including patients diagnosed with GVHD treated with ruxolitinib from January 2017 to October 2018. Demographic and clinical data were collected from electronic medical records and pharmacy software: sex, age, weight, type, location and severity of GVHD, previous treatments, dosing, duration of treatment, response and toxicities.

Results Seven patients were included, 5 boys and 2 girls, with a median age of 11 years (5–18); and a median weight of 40 kg (15–63). One patient developed severe acute intestinal GVHD (aGVHD) and six chronic GVHD (cGVHD), moderate (n=1) and severe (n=5). The median number of affected organs per patient was three (1–4): skin (n=6), gastrointestinal tract (n=4), joints (n=2), lungs (n=2) and liver (n=1).

Median number of treatments used before ruxolitinib was four (2–5), always including corticosteroids as the first option. Treatments in the second or third line were: extracorporeal photoapheresis, mesenchymal stem cells, immunosuppressants and infliximab.

Four patients started with 5 mg/12 hour increasing to 10 mg/12 hour if they weighed >25 kg. One started at 1.25 mg/12 hour because they were in treatment with posaconazole increasing to 2.5 mg/12 hour, and two started directly at 10 mg/12 hour. The median treatment's duration was 10 months (3–19). All cGVHD were still in treatment at the end of the study.

All patients responded to ruxolitinib: the only patient with aGVHD and one patient with cGVHD had complete response, and the remainder had partial response.

Digestive, cutaneous and joints symptoms showed improvement, while GVHD affecting the lungs and liver did not.

No patient died during the study. Only two patients presented with leukopenia and two suffered reactivations of cytomegalovirus, but there was no dose reduction due to toxicity.

Conclusion In our patients ruxolitinib has proven to be an effective and safe treatment option, but well-designed clinical trials are necessary to know its real benefit in paediatric patients with steroid-refractory GVHD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thank you to all authors for their involvement.

No conflict of interest.

4CPS-132 INTERACTIONS BETWEEN ALTERNATIVE THERAPIES AND PRODUCTS IN CLINICAL TRIAL IN ONCO-HAEMATOLOGY

A Toulemonde*, C Bensoussan, C Davoine, F Cartier, I Madelaine. Hôpital St. Louis, Pharmacy, Paris, France

10.1136/ejhp-pharm-2019-eahpconf.281

Background The development of oral cancer treatments (OCT) is sizeable, with many molecules in clinical trials. More and more patients wish to combine OCT to alternative therapy products (to reduce side effects, improve therapeutic effects). However, their use is associated with risks when combined with OCT: additional toxicities, drug interactions. Dispensing drugs included in clinical trials, the hospital pharmacist is responsible for their proper use, particularly the lack of interaction, with the help of documents supplied by the sponsor (investigator's brochure, protocol and prescription forms).

Purpose The main objective of this study was to analyse information given by sponsors on the use of alternative therapy products in association with OCT in clinical trials.

Material and methods We did an inventory of all documents given by sponsors checking if the use of alternative therapy products were mentioned. They were recorded qualitatively and quantitatively, and their readability has been assessed as easy (<5 min), mild (5–10 min) or complex (>10 min).

Results The study was completed in our centre in May 2018, including 73 active trials with at least one OCT (61 OCT in monotherapy, 11 in bitherapy and one in tritherapy). Thirty-four trials (56%) in haematology, seven in onco-dermatology, the others for solid tumours. At least one information related to alternative therapy products was found in 57% of protocols, 14% of investigator's brochure and 4% of prescription forms. Grapefruit was mentioned in 72% of documents, 76% for St. John's Wort and 30% for bitter oranges. The other alternative therapy products were mentioned in less than 8% of documents. Only two protocols mention possible interaction with 'herbal medicines products'. In more than 70% of cases, the information was easy to find. The protocol is the document where information was the most easily readable (92%).

Conclusion The key document to find information on alternative therapy products is the protocol, where information is easily readable. However, only grapefruit and St John's Wort are mentioned in the main cases. In view of their rising uses, additional training should be offered to the pharmacist and a particular mention should be indicated on the prescription