**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

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

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**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 posaconazol 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 ruxolotinib: 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 leukopaenia 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*

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**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

form, as a routine document, circulating between patient, doctor and pharmacist.


### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.


## 4CPS-133 DARATUMUMAB (DARZALEX) FOR THE TREATMENT OF MULTIPLE MYELOMA IN A THIRD-LEVEL HOSPITAL: VARIABILITY OF USE AND EFFECTIVENESS


S Gonzalez Suarez*, AR Rubio Salvador, AA García Sacristán, A Dominguez Barahona, R López Álvarez, C Blázquez Romero, N Labrador Andújar, P Moya Gómez. *Hospital Virgen de la Salud, Hospital Pharmacy, Toledo, Spain*


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**Background** Daratumumab is a human monoclonal antibody that binds to CD38 protein, expressed in a high level in the tumour cells of multiple myeloma (MM), inhibiting their proliferation. It has been authorised in combination with bortezomib, melphalan and prednisone for newly diagnosed MM not candidates for an autologous haematopoietic stem cell transplant or in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for patients who have received at least one previous treatment and in monotherapy for adult patients with MM relapsed and refractory to treatment, who have previously received a proteasome inhibitor and an immunomodulatory.

**Purpose** Assessment of prescription profile of Daratumumab for the treatment of MM in a third-level hospital and the effectiveness of different regimens in terms of progression-free survival (PFS).

**Material and methods** Retrospective review of patients with MM who received treatment with Daratumumab from February 2017 to October 2018. Data were collected from the electronic prescribing system for Oncology Haematology patients, and electronic medical records.

**Results** Ten patients received treatment with Daratumumab (60% males, 40% females, median age 68 years).

DLd (daratumumab 16 mg/kg, lenalidomide 10 mg or 25 mg, dexamethasone 40 mg) every 28 days was prescribed for five patients (50%), one as first-line, one as second-line and three as third-line treatment. Median PFS was 10 months for the group of patients treated.

Daratumumab 16 mg/kg monotherapy weekly every 28 days was prescribed for two patients (20%) both as third-line treatment and who died after 1 month of treatment.

DABODEX regimen (Daratumumab 16 mg/kg, bortezomib 1.3 mg/m$^2$, dexamethasone 20 mg) every 28 days was prescribed for three patients (30%), one as first-line treatment, one as second-line and one as third-line. Median PFS was 6 months in this group.

**Conclusion** Prescription profile of Daratumumab for the treatment of MM in our series of patients is variable, with different scenarios of treatment and different results in terms of PFS.

It is mandatory to update protocols in the use of daratumumab in our hospital to measure its use among different drug options, most importantly with promising therapeutic advances recently authorised for MM treatment.


### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.


## 4CPS-134 HEALTH- RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS TREATED WITH DISEASE-MODIFYING THERAPIES


[1]AM Horta Hernandez*, [1]M Blanco Crespo, [2]A Yusta Izquierdo, [3]B Escalera Izquierdo. *[1]Guadalajara University Hospital, Pharmacy Department, Guadalajara, Spain; [2]Guadalajara University Hospital, Neurology Department, Guadalajara, Spain; [3]Pharmacy School Alcalá University, Pharmaceutical Technology Department, Alcalá de Henares, Spain*


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**Background** The Multiple Sclerosis Quality of Life-54 (MSQoL-54) questionnaire is a multidimensional health-related quality of life (HRQoL) measure that combines both generic and MS-specific items into a single instrument. It provides physical health composite score (PCS) and mental health composite score (MCS) expressed on a scale of 0 (poorest QoL) to 100 (best possible QoL).

**Purpose** To evaluate HRQoL calculating PCS and MCS. To analyse differences in HRQoL considering Expanded Disability Status Scale (EDSS) and disease modifying therapies (DMTs). Disability was considered mild with EDSS (0–3.5) and moderate with EDSS (4–6.5).

**Material and methods** Prospective study from March to September 2017. MS patients treated with DMTs completed MSQoL-54. Clinical data were collected from electronic medical records. DMTs were classified considering route of administration: intravenous (IV, Natalizumab), oral (Fingolimod, Dimethylfumarate, Teriflunomide) and intramuscular (IM) +subcutaneous (SC): Interferon (IFN) +Glatiramer Acetate (GA). Statistical analysis was made with Wilkinson Test and tstudent *t*-test using SPSS 15.0.

**Results** One-hundred and twenty-two patients completed the questionnaire (74% female). Median age was 43.5 (IQR: 37–52.7); 93% of patients had relapsing-remitting MS. Median disease duration was 8.5 years (IQR: 5–13). Eighty per cent had mild EDSS and 20% had moderate EDSS. Seventy-one were treated with IM+SC DMT, 32 with oral and 19 with IV. Median EDSS were: 1.5 (IQR: 1–2) in IM+SC group, two (IQR: 1–2,5) in oral group and three (IQR: 2–4,5) in the IV group. Statistically significant differences in PCS ($p<0.003$) and MCS ($p<0.01$) were found in patients with mild and moderate EDSS in all groups of treatment. Differences were found in PCS ($p<0.03$) between IV and IM+SC and MCS ($p<0.01$) between the IV and the other groups. Considering both EDSS and DMT route of administration, there were no differences in PCS: MCS significance was found just in mild EDSS ($p<0.01$).

**Conclusion** Mild and moderate EDSS affected HRQoL in both PCS and MCS.

Considering the route of administration, there were differences in PCS between Natalizumab and IFN+GA group and in MCS between Natalizumab and the rest. This could be explained due to higher EDSS in Natalizumab patients.

Analysis including disability and route of administration showed statistical significance just in MCS in patients with mild EDSS.

Disability degree negatively affected HRQoL independently of DMT route of administration.


### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.