The association of PIM with AE was determined by OR and the χ^2 test or Fisher's exact probability test.

Results Sixty-four patients were treated with HDMTX for 160 cycles with a median HDMTX dose of 11760 mg (IQR 3370–14 207.5 mg). Median age was 66.4 years (IQR 55.6–75.3) and 42.2% were women. Eleven patients were treated for leukaemia and 53 for lymphoma.

Median baseline creatinine was 0.66 (IQR 0.57–0.78) mg/dL. AE was present in 80 cycles (50%). In 91.3% of these, patients were receiving concomitant PIM with methotrexate elimination. In 52 cycles methotrexate elimination was altered only after 72 hours.

PIM associated with AE were: levetiracetam (OR=6.9, 95% CI 1.5–32.4; p<0.05), non-steroidal anti-inflammatory drugs (OR=10.9, 95% CI 2.4–49.4; p<0.05) and doxycycline (OR=0.5, 95% CI 0.4–0.6; p<0.05). There were no significant differences between use of proton pump inhibitors, loop diuretics, amphotericin B, penicillin and derivate, aminoglycosides, ciprofloxacin or p-glycoprotein/ABCB1 inhibitors.

Conclusion and relevance There was a high prevalence of patients with AE of HDMTX. Potentially interacting medications with HDMTX are frequently used during treatment. Only levetiracetam and non-steroidal anti-inflammatory drugs were associated with methotrexate AE in our patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-045 OLARATUMAB: WHAT IS THE ECONOMIC IMPACT ON THE NATIONAL HEALTH SYSTEM?

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Background and importance The US Food and Drug Administration (FDA) granted olaratumab (human anti-PDGFRα monoclonal antibody) fast track authorisation in November 2016 to treat advanced soft tissue sarcoma (STM). Also, the European Medicines Agency (EMA) allowed conditional marketing authorisation for this drug after the phase 1b/2 trial. In the post-authorisation phase III trial ANNOUNCE, data were limited because of the small number of patients included and the lack of confirmation of efficacy and clinical benefit. Consequently, the EMA banned the treatment of new patients with olaratumab.

Aim and objectives We studied the economic impact of olaratumab on the National Health Service (NHS) for our hospital patients, from its introduction in our country (November 2017) to the EMA ban (January 2019).

Material and methods A retrospective analysis was conducted. In our hospital 17 patients, 11 of which were women (64.7%), with a mean age of 54.7±24.5 years, were treated with olaratumab. Data (weight and doses prescribed) were extracted from our chemotherapy prescriptions and preparations database software. We selected patients treated with olaratumab.

Results An olaratumab vial cost € 1375 (€ 2.75/mg). The recommended dose was 15 mg/kg on days 1+8 of each 21 day cycle. Between November 2017 and January 2019, in our hospital, 17 patients completed 79 total cycles for a total cost of € 457 035.

The primary outcome of the authorisation study showed a better progression free survival (6.6 months). Only five of our patients exceeded this period and had to discontinued treatment because of progression of disease. The total cost of their therapy was € 294 596 (48 total cycles for 5 patients). For the other 12 patients, the cost was € 162 439 (31 total cycles). The average cost of administration to the NHS was € 2815/patient.

Conclusion and relevance After conditional marketing authorisation, further research costs of the approved drug are necessarily at the expense of the NHS. This was the case for olaratumab, that resulted in it not being effective. For this reason, for fast track authorisation, the reimbursement price of the drugs should be taken into account in the post-authorisation costs. Furthermore, it is important to provide hospital monitoring of the clinical effects of the drug and consequent cost.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2. ClinicalTrials.gov Identifier: NCT01185964

No conflict of interest.

5PSQ-046 PREVALENCE OF NIVOLUMAB ADVERSE EVENTS IN ROUTINE CLINICAL PRACTICE

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Background and importance Nivolumab was authorised in Spain in 2015. It is a human immunoglobulin monoclonal antibody that binds to PD-1 receptor and blocks its interaction with PD-L1 and PD-L2. It is indicated in adjuvant or metastatic melanoma (MC), metastatic non-small cell lung cancer (NSCLC), renal cell carcinoma (RC) and squamous cell carcinoma of the head and neck (HNC), among others. Its recent commercialisation means there are no data on adverse events (AE) following long term treatment in routine clinical practice.

Aim and objectives To assess the tolerability of nivolumab, to identify and calculate the prevalence of AE related to nivolumab and to compare its frequency with the that described on the data sheet (DS).

Material and methods A descriptive, retrospective, observational study was carried out from March 2016 to September 2019 in a tertiary hospital. It included all patients treated with nivolumab since it was commercialised. Medical records and blood tests of all treated patients were reviewed from the start of nivolumab treatment. Information was collected from the applications Abucasis, Mizar, Farmis-Oncofarm and Gestlab. Variables collected were sex, age, diagnosis, number of nivolumab doses, AE, if the patient died, nivolumab start/end date and reason for stopping treatment. AE were classified according the prevalence described on the DS: very common (>10%), common (1–10%), not common (0.1–1%), rare (0.01–0.1%) and very rare (<0.01%).

Results A total of 48 patients were included, 77% were men and median age was 63 years. The main diagnoses were NSCLC (40%), followed by RC (29%), MC (21%) and HNC