Material and Methods Observational, single-centre, retrospective study, which included all oncohaematological CT whose experimental intervention involved the use of ICI initiated in a tertiary hospital from January 2018 to December 2022. Expansion studies were excluded. The following variables were collected: neoplasm, locations (unicentre/multicentre; national/international), ICI, intervention (monotherapy/combination), control (yes/no), phase, clinical context (adjuvant/neoadjuvant/locally advanced/metastatic/haematological malignancy with curative intent/haematological malignancy with palliative intent), intention (curative/palliative), inclusion criteria for PLWHIV (explicitly excluded/conditional inclusion/not mentioned) and, among conditional inclusion, conditions established (viral load/antiretroviral treatment/lymphocyte count). Data were extracted from clinicaltrials.gov, the EU Clinical Trials Register and the Spanish CT Register.

Results One hundred and twenty-six CTs were identified, of which 123 (97.6%) involved solid tumours. The most studied neoplasms were lung cancer (n=17; 13.5%), basket trials (n=16; 12.7%) and melanoma (n=14; 11.1%).CTs were mainly international (n=114; 90.5%) and multicentre (n=125; 99.2%). The intervention consisted of ICI combined with other agents (n=89; 70.6%), ICI monotherapy (n=25; 19.8%), and ICI dual therapy (n=22; 17.5%). Pembrolizumab was the most frequently studied ICI (n=34; 27.0%), followed by atezolizumab (n=22; 17.5%) and nivolumab (n=20; 15.9%). Seventy (55.6%) CT were controlled. Sixty-three were phase II (n=63; 50.0%), III (51; 40.5%), and I (n=12; 9.5%). Most were conducted in the metastatic setting (n=98; 77.8%) and with palliative intent (n=103; 81.7%).PLWHIV were explicitly excluded from 91 (72.2%), 24 (19.0%) did not mention HIV infection among their inclusion/exclusion criteria, and 11 (8.7%) allowed the inclusion of PLWHIV if certain conditions were met regarding viral load (n=6; 54.5%), antiretroviral treatment (n=8; 72.7%), lymphocyte count (n=6; 54.5%), and 3 (27.3%) stated adequate HIV control, without further detail.

Conclusion and Relevance PLWHIV are frequently excluded from oncohaematological CTs testing ICI.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-032 ADJUSTED INDIRECT COMPARISON OF CEMIPLIMAB IN COMBINATION WITH CHEMOTHERAPY VS IMMUNOTHERAPY ALONE IN THE FIRST-LINE TREATMENT OF METASTATIC NON-SMALL-CELL LUNG CANCER IN PATIENTS WITH PD-L1≥50%

[1]A Aguado Paredes*, [2]EJ Alegre Del Rey. [1]*Clinical Pharmacist, Hospital Universitario Virgen Macarena, Sevilla, Spain*; [2]*Hospital Universitario Puerto Real, Clinical Pharmacy, Cádiz, Spain*

10.1136/ejhpharm-2024-eahp.494

Background and Importance Cemiplimab with chemotherapy is licensed for the treatment of first line adult patients with locally advanced NSCLC who are not candidates for chemoradiation, or metastatic, expressing PD-L1≥1%. Cemiplimab alone has the same indication in patients expressing PD-L1≥50%. Pembrolizumab and atezolizumab are also indicated in metastatic stage in patients with PD-L1≥50%.

Aim and Objectives To know whether cemiplimab in combination with chemotherapy (ct) and mono-immunotherapy can be declared equivalent therapeutic alternatives (ETA).

Material and Methods A literature search was performed in MEDLINE-PubMed for phase III randomised clinical trials (CT)with similar population and duration. An adjusted indirect comparison (IC)was performed using Bucher's method (ITC calculator). The primary endpoint was overall survival in patients with PD-L1≥50%. Therapeutic alternatives were compared with cemiplimab monotherapy. The delta value (Δ), maximum clinically irrelevant difference, was taken as the value from the ESMO-MCBS Guidelines to consider substantial benefit, HR 0.70 and its inverse 1.43 . To declare them as ETA, the GENESIS-GHEMA guidelines were applied.

Results Data from CT against a common comparator, platinum-based chemotherapy, were included. The studies were similar, although the CT of cemiplimab-chemotherapy and cemiplimab included patients with stage IIIB, IIIC and IV, while the other CT only included stage IV; furthermore, the CT of cemiplimab excluded never-smokers (less than 100 cigarettes through life), and the small amount of never-smokers included on other monotherapy trials showed uncertain benefits. The following results were obtained: HR (cemiplimab vs cemiplimab+ct) 0.93 [95%CI 0.52–1.68] p 0.81; HR (cemiplimab vs pembrolizumab) 0.95 [95%CI 0.58–1.55] p 0.84; HR (cemiplimab vs atezolizumab) 0.97 [95%CI 0.59–1.60] p 0.89.

According to the ETA guidelines, cemiplimab+ct, atezolizumab, pembrolizumab and cemiplimab showed 'probable clinical equivalence'. Clinically relevant differences between them cannot be discarded, since the confidence intervals exceed the equivalence margins, but this occurs at both extremes, and they can be considered as alternatives with similar effectiveness. Cemiplimab+ct presents a comparative handicap on safety because of the toxicity of chemotherapy.

Conclusion and Relevance In this setting, atezolizumab, cemiplimab and pembrolizumab monotherapies can be positioned as ETA; their selection should be based on economic comparisons. Among the never-smoker subpopulation, the comparative effectiveness between immune-chemotherapy and mono-immunotherapy should be assessed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-033 ADJUSTED INDIRECT COMPARISON OF CEMIPLIMAB IN COMBINATION WITH CHEMOTHERAPY VS IMMUNOTHERAPY ALONE IN THE FIRST-LINE TREATMENT OF METASTATIC NON-SMALL-CELL LUNG CANCER IN PATIENTS WITH PD-L1≥1%

[1]A Aguado Paredes*, [2]EJ Alegre Del Rey. [1]*Hospital Universitario Virgen Macarena, Clinical Pharmacy, Sevilla, Spain*; [2]*Hospital Universitario Puerto Real, Clinical Pharmacy, Cádiz, Spain*

10.1136/ejhpharm-2024-eahp.495

Background and Importance Cemiplimab, pembrolizumab, atezolizumab ± bevacizumab, nivolumab + ipilimumab and durvalumab + tremelimumab in combination with chemotherapy, and nivolumab + ipilimumab, are licensed for the treatment of 1L adult patients with metastatic NSCLC expressing PD-L1≥1%.

Aim and Objectives To know if the combinations of immunotherapy and chemotherapy (ct) can be declared equivalent therapeutic alternatives (ETA).