double-blind), number of patients included (abemaciclib N=5637 vs palbociclib N=1250), treatment duration (abemaciclib two years vs palbociclib one year) and percentage of patients pretreated with taxane, anthracycline or both (abemaciclib 37% vs palbociclib 99%). Clinical trials were not similar due to these differences.

Abemaciclib was effective in HER2-negative, high risk and luminal EBC. However, palbociclib was not. IDFS abemaciclib group was statistically significant (HR=0.70; 95% CI: 0.59-0.82; p<0.0001) with a median follow-up of 27 months (90% patients completed treatment). In contrast, IDFS palbociclib group was not statistically significant (HR=0.93; 95% CI: 0.74-1.17; p=0.525) with a median follow-up of 43 months (92% patients completed treatment).

Regarding consist results, 2-year IDFS rate was different too: abemaciclib 93% vs palpociclib 88%. In short, relevant methodological limitations were detected so adjusted ITC was not possible.

Conclusion and Relevance Abemaciclib and palbociclib cannot be considered ETA in HER2-negative, high risk and luminal EBC, although abemaciclib demonstrated efficacy as adjuvant treatment in these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-010 EVOLUTION OF ONCO-HAEMATOLOGICAL CLINICAL TRIALS FROM 2016 TO 2021: EXPERIENCE FROM A TERTIARY HOSPITAL

H Martinez Barros, Á Díaz Gago, M Rodriguez Marin, E Gemeno Lopez*, C Pueyo López, M Lavandeira Perez, A Poveda Escolar, AM Alvarez Dian. *Hospital Universitario Ramon Y Cajal, Pharmacy, Madrid, Spain*

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Background and Importance Previous work has described changes in the trends in onco-haematological clinical trials in recent years, describing an increase in the use of surrogate endpoints, changes in their funding or a greater number of non-randomised trials (1, 2).

Aim and Objectives To describe and compare the characteristics of onco-haematological clinical trials opened in a tertiary hospital in 2016 and 2021.

Material and Methods All interventional clinical trials initiated in our hospital in 2016 and 2021 were included. The following variables were collected: title, funding, tumour site, blinding, control, randomisation and primary endpoint. Data were compared using the Pearson $\chi 2$. Results were deemed statistically significant at p<0.05. Statistical analysis was performed using STATA (StataCorp, Texas, USA).

Results We found 89 interventional clinical trials started in 2016 and 71 studies in 2021. The majority were in the Medical Oncology service (93.6% and 83.1%). Breast cancer accounted for the largest number of trials initiated (22.5% and 19.7%). In both study periods, most clinical trials were industry-sponsored, with an increase over time (82.0% vs 94.4%; p=0.019). More than half of the studies initiated were controlled (58.4% vs 54.9%; p>0.05), randomised (59.6% vs 66.2%; p>0.05) and open-label (78.7% vs 67.6%; p>0.05), with no statistically significant differences between 2016 and 2021. An increase in the number of phase 3 clinical trials was observed (37.0 vs 54.9%; p = 0.017), with a predominance of open-label design (54.6% vs 51.3%; p>0.05) and the use of surrogate endpoints as primary outcomes (54.5 vs 69.2%; p>0.05). No trial had quality of life as a primary endpoint

Conclusion and Relevance Most phase 3 clinical trials used an open-label design and surrogate endpoints as primary outcomes.

Although this is a single-centre analysis, some trends observed by other authors, such as a higher number of industry-sponsored studies, were observed.

None of the 160 clinical trials initiated had quality of life as a primary endpoint.

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Conflict of Interest No conflict of interest.

6ER-011 EFFICACY OF THERAPIES IN NON-SMALL-CELL LUNG CANCER WITH EGFR EXON 20 INSERTION MUTATIONS: A SYSTEMATIC REVIEW

[1]MD Gil-Sierra, [2]MDP Briceño Casado*, [1]C Moreno-Ramos, [1]MA Blanco-Castaño, [3]CM Cuadros-Martinez. *[1]Hospital Universitario de Puerto Real, Pharmacy, Puerto Real, Spain; [2]Hospital Universitario de Jerez de la Frontera, Hospital Pharmacy, Jerez de la Frontera Cádiz, Spain; [3]Hospital Universitario de Jerez de la Frontera, Pharmacy, Jerez de la Frontera, Spain*

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Background and Importance Patients with non-small-cell lung cancer (NSCLC) and epidermal growth factor receptor (EGFR) exon 20 insertion mutations have poor prognosis and few therapeutic alternatives.

Aim and Objectives To develop a systematic review of platinum pre-treated NSCLC harbouring eGFR exon 20 insertions to assess efficacy of treatments and scientific quality of studies.

Material and Methods Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA) guidelines was applied in bibliographic review. Search was conducted in PubMed® database up to 15 September 2022. Filter 'clinical trial' on types of articles was applied to the following review strategy: (exon 20 insertion) AND (Therapy/broad[filter]). Inclusion criteria: Randomised clinical trials (RCTs) evaluating treatments in patients diagnosed with advanced or metastatic NSCLC harbouring EGFR exon 20 insertions who had previously received platinum-based chemotherapy. Efficacy endpoints considered were objective response rate (ORR), progression-free survival (PFS) and overall survival (OS). Data recorded: publication date, study design, comparator arm, therapies, sample size, treatment line, efficacy data.

Results Forty search results were found in review. Twelve RCTs were included. Publication dates of studies were between April 2015 and July 2022. Design of studies: 9 (75%) phase II RCT (one was basket trial) and 3 (25%) phase I/II. None of them presented a comparator arm. Therapies assessed: poziotinib, osimertinib (high and low doses), pertuzumab-trastuzumab combination, mobocertinib, amivantamab, erlotinib-onalespib combination, luminespib, ado-trastuzumab emtansine and dacomitinib. Sample size of RCTs ranged from 10 to 114 patients. Both untreated and platinum-pretreated patients were recruited in 4 (25%) RCTs and the rest