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

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

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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

comprised exclusively platinum-pretreated population. Ado-trastuzumab emtansine showed the best numerical results according to ORR (54.5%), but the worst PFS (2.8 months; 95% CI 1.4-4.4) and OS (8.1 months; 95% CI 3.5-13.2) of all therapeutic alternatives. The highest numerical efficacy results were achieved by amivantamab [PFS = 8.3 months (95% CI 6.5-10.9); OS = 22.8 months (95% CI 14.6 to not reached)] and mobocertinib [PFS = 7.3 months (95% CI 5.5-9.2); OS = 24.0 months (95% CI, 14.6-28.8)].

Conclusion and Relevance Results of amivantamab and mobocertinib suggested a higher numerical efficacy for clinically relevant endpoints in platinum pre-treated NSCLC harbouring EGFR exon 20 insertions. However, comparative RCTs with larger sample sizes are necessary to obtain reliable data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-017 STRUCTURED OBJECTIVE CLINICAL EVALUATION FOR PHARMACY STUDENTS ON INTERNSHIPS AT THE HOSPITAL

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Background and Importance Structured assessment for final year students is a teaching tool based on the Miller´s Pyramid that has been implemented in Spain for many years. To carry out this evaluation system for students doing internships in the hospital's Pharmacy Service is very innovative.

Aim and Objectives To describe the process of designing a structured evaluation for students who are doing their internship in the hospital Pharmacy Service. The purpose of the objective assessment is to verify that the students can demonstrate what they have learned during their hospital practice. To do this, different clinical skills and technical skills will be evaluated, simulating real situations related to the work of the Pharmacy Service.

Material and Methods Six tests have been established: pharmaceutical care for outpatients, validation of medical prescriptions, stock management, reconciliation of medication on admission, preparation of a master formula and oncology pharmacy. All tests are related to daily assistance activities of the hospital pharmacy. In each test, the student has a limited time to perform the task that is indicated. The qualification method is totally objective, through a previously defined checklist. A schedule has been scheduled for everything to be ready in January 2023.

Results The objective clinical evaluation has been structured in 6 tests, in which a total of 24 students may be examined. The presence of 6 evaluators and 3 actors will be necessary. The cost of each test will be minimal because most of the materials are donations from pharmaceutical laboratories and other companies. The qualification is immediate, and the duration of the test will be about 3 hours. The checklist of each test will be reviewed by two evaluators, and must include items on clinical, technical and interprofessional communication skills.

Conclusion and Relevance The clinical evaluation system for internship students in the pharmacy service is expected to be very useful for pharmacists in the Pharmacy Service. Thanks to this exam they will have objective information about their teaching role with these students, thus detecting points for improvement. In addition, the student learns about clinical reasoning, decision-making , problem solving, and interpersonal relationship skills.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-019 THE STUDENT PHARMACIST EXPERIENCE OF ENHANCED CLINICAL PLACEMENTS

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Background and Importance The role of a pharmacist is ever-expanding with an increasing need for the provision of enhanced health services. In response to the General Pharmaceutical Council's recent announcement for 'prescribing ready' pharmacy graduates by 2025, Health Education England has, this year, broadened the clinical tariff for education providers to include pharmacy giving an opportunity to enhance the clinical placements offered to pharmacy students in the UK.

Aim and Objectives The aim of this project was to assess the overall experience students had on an Enhanced Clinical Placements over a variety of clinical settings.

Material and Methods The placement was patient-facing (5-days) under the primary supervision of a prescriber, with a pre-placement induction (15 hours of blended learning) consisting of simulated clinical activities, and a post-placement conference (1 day). During the placement, students had the opportunity to develop an extended range of clinical skills and observe and discuss the prescribing decisions made by their prescribing supervisor which are currently outside the scope of the pharmacy degree.

Two focus groups (n=10 and n=9) were held with students at the post-placement conference. Students were asked about their induction and placement experience. Focus groups were transcribed and analysed using Thematic Analysis.

Results Four main themes emerged from the data, which were named Variety, Consolidation of prior learning, Professional identity, and Logistics. Students expressed an appreciation for the ECP in providing them with additional clinical experience over a wider variety of settings than they had seen before. There was a recognition that the ECP helped to consolidate learning they had gained on the taught courses and that it heightened their professional identity but students also raised some areas for improvement in terms of the general logistics of the placement.

Conclusion and Relevance This was a useful exercise to provide students with a range of experiences, helping them to promote an understanding of their professional value and role within a multi-disciplinary team. Future implementation needs to consider the level of standardisation between placements