6ER-027 ECONOMIC BENEFIT AND CLINICAL ADVANTAGES WITH THE INCLUSION OF PATIENTS IN CLINICAL TRIALS RELATED TO PARAMYLOIDOSIS

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10.1136/ejhpharm-2024-eahp.489

Background and Importance Access to innovative medicines requires extensive and careful pharmaco-economic evaluation.

The inclusion of patients in Clinical Trials (CT) allows early access to new experimental medicines and considerable economic saving for the healthcare system.

Aim and Objectives Evaluate the economic benefit of including patients with hereditary transthyretin amyloidosis (hATTR) in clinical trials between 2018 and 2023.

Material and Methods Retrospective analysis of paramyloidosis-related clinical trials taking place at the centre since 2018. The data collected were the number of paramyloidosis-related CT, the number of patients included the time of participation in the CT and the average price of conventional treatment.

Results At our Clinical Trials Unit there are currently 6 Paramyloidosis-related CT underway, involving a total of 65 patients.

In economic terms, patient participation on ongoing CT related to Paramyloidosis has led to a cumulative saving of 15,667,487.98€ , compared to the costs of conventional therapy (tafamidis[1],inotersen[2] and patisiran[3]).

The distribution of annual savings was:

- 2019: 644.396,70€
- 2020: 2.447.335,64€
- 2021: 4.465.670,09€
- 2022: 4.206.997,00€
- August of 2023: 3.903.088,55 €

Conclusion and Relevance Participation in CT allows early access to new experimental therapies and contributes to the development of new drugs and/or new therapeutic indications. In Paramyloidosis, new agents like TTR stabilisers, subcutaneous antisense oligonucleotides and iRNA therapies are potential new alternatives.[4]

By participating in CT, centres obtain an extra source of funding. The participation of patients in CT also allows for a reduction in costs, through the preservation of financial resources and medication.

The savings generated by the participation in CT help to provide better care and an efficiency healthcare system.

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Conflict of Interest No conflict of interest.

6ER-028 REAL-WORLD TREATMENT PATTERN AND EFFECTIVENESS OF PIRFENIDONE AND NINTEDANIB IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS: A MULTI-INSTITUTIONAL STUDY IN TAIWAN

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10.1136/ejhpharm-2024-eahp.490

Background and Importance Pirfenidone and nintedanib have been proven survival benefits and been currently approved for idiopathic pulmonary fibrosis (IPF). However, real-world comparison of effectiveness between two antifibrotics remains limited in Asia.

Aim and Objectives Our study was aimed to assess: (1) factors associated with the choice of pirfenidone versus nintedanib; (2) dose modification during treatment; (3) overall survival (OS).

Material and Methods We conducted a retrospective cohort study by using the largest multi-institutional electronic medical records in Taiwan. We included IPF patients newly receiving pirfenidone or nintedanib during 2018–2020. We followed up included patients to death, loss of follow-up or December 2022. The clinical factors included age, sex, lung function, biochemical data, comorbidities and co-medications. Multiple logistic regression analysis was used to assess factors associated with drug choice. Dose modification was assessed every 3 months by using dose intensity in follow-up period based on as-treated analysis. In OS analysis, we applied probability of treatment weighting (IPTW) and Cox regression model to enhance the comparability of study subjects and estimate hazard ratio (HR) between two treatment groups, respectively.

Results A total of 86 patients receiving pirfenidone and 142 patients receiving nintedanib. Mean age and Forced vital capacity (FVC) were 70.7 11.3 years and 68.8 17.4%, respectively. The use of nintedanib was positively associated with the patients with chronic kidney disease (CKD) (odds ratio: 2.1, 95% CI: 1.06 – 4.18). Dose reduction rate was similar between two groups (59.3% vs. 65.4%, P = 0.34). After a median of 25.5 months follow-up, nintedanib users were associated with worsen OS than pirfenidone users (adjusted HR: 2.07, 95% CI: 1.24 – 3.45).

Conclusion and Relevance Our study showed CKD patients were likely prescribed nintedanib. Pirfenidone users had association of better all-cause mortality than nintedanib users. Further studies are suggested to confirm our findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-029 A SYSTEMATIC REVIEW OF COMBINED POLY (ADP-RIBOSE) POLYMERASE INHIBITOR AND ANDROGEN RECEPTOR ANTAGONISTS IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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10.1136/ejhpharm-2024-eahp.491

Background and Importance According to latest practice guideline, concurrent administration of poly (ADP-ribose) polymerase inhibitors (PARPi) and androgen deprivation therapy (ADT) may have synergistic efficacy for metastatic castration-resistant prostate cancer (mCRPC) patients. However, the effectiveness of PARPi and ADT was highly depended on mCRPC patients' heterogeneous gene status. To move toward precision medicine in mCRPC treatment, high level of evidence summarising newest clinical trials was unmet need.
Aim and Objectives To conduct a systematic review and meta-analysis to estimate effectiveness of PARP inhibitors combined with ADT versus standard ADT in the mCRPC patients with homologous recombination repair (HRR) positive and negative.
Material and Methods We searched PubMed, Embase and Cochrane databases from 2009 to September 2023 for all randomised clinical trials. No language or other restrictions were imposed on the searches. Two review authors independently screened the titles and abstracts of each trial before obtaining the full text for all potentially eligible trials and assessed the included trials for risk of bias. The outcomes included progression free survival and overall survival among all patients, HRR+ and HRR-. A fixed-effects meta-analysis was applied to pool hazard ratio (HR) with 95% confidence intervals (CIs).
Results A total of five studies with a total of 1207 PARPi and 1206 placebo patients were included. Compared to standard ADT, the PARPi plus ADT was associated with a 38% PFS improvement (HR: 0.62; 95% CI: 0.54–0.72) and OS prolong (HR: 0.85, 0.73–0.99) in the overall patients. Among HRR+ patients, the pooled PFS and OS were 0.65 (0.52–0.81) and 0.66 (0.45–0.95), respectively. Among HRR- patients, the pooled PFS and OS were 0.74 (0.59–0.92) and 0.89 (0.70–1.14), respectively.
Conclusion and relevance Based on current evidence, we suggest that the combination of PARPi and ADT in patients with mCRPC to significantly improved both progression-free survival and overall survival rates, especially for HRR+ patients. As hospital pharmacists, we play an auxiliary role in shared decision-making system. We can use skill of evidence-based medicine to integrate and explain evidence and provide patients with more precisely and effectively therapeutic strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-030 EVALUATION OF A GROUP-BASED ONLINE INFORMED CONSENT CONVERSATION (ECONSENT) IN PARTICIPANTS FROM A VACCINATION CLINICAL TRIAL: A MIXED METHOD STUDY

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10.1136/ejhpharm-2024-eahp.492

Background and Importance Use of digital consent (eConsent) has expanded in the last few years in Europe especially during the pandemic. Slow recruitment rate and limitation in reaching out to participants from different backgrounds are the challenges often faced in clinical research. Given the benefits of eConsent and group counselling reported in the literature, group eConsent was implemented in study recruitment for the SWITCH-ON trial.
Aim and Objectives We aim to explore the experience of participants who attended group eConsent for the SWITCH-ON study and evaluate its potential for future use.
Material and Methods SWITCH-ON study aims to analyse the immunogenicity of healthy population following bivalent COVID-19 booster vaccination. 434 healthcare workers aged between 18 and 65 were successfully recruited and were sent a questionnaire about their experience with group eConsent after their informed consent session. Out of 399 completed questionnaires received (response rate 92%), 39 participants did not join group eConsent. The remaining 360 responses were included in the final analysis. Quantitative and qualitative data were reported using descriptive statistical analysis and thematic analysis respectively.
Results Participants found group eConsent efficient, useful to hear questions from others and being in a group created a sense of togetherness. However, limited privacy, barriers to ask questions in a group and peer pressure can limit the use of group eConsent. 165 (46%) participants thought that group eConsent was also suitable to recruit participants with disease or conditions while 87 (24%) reported limitations with this method. The remaining participants suggested that applicability of group eConsent depended on the diseases or conditions of the study population and one-to-one conversation should always be available. Participants who had experience both one-to-one and group eConsent shared different preferred consent formats for future studies.
Conclusion and Relevance Group eConsent can be an effective tool for research recruitment with further optimisations to overcome the limitations raised by participants. Using webinars to providegeneral information about the study, followed by an individual session for each participant will retain the benefits of group eConsent and minimise the limitations it posed. This proposed setting will address the privacy questions and makes group eConsent easier to be implemented in many study populations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-031 EXCLUSION OF PEOPLE LIVING WITH HIV FROM ONCOHAEMATOLOGICAL CLINICAL TRIALS WITH IMMUNE CHECKPOINT INHIBITORS

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10.1136/ejhpharm-2024-eahp.493

Background and Importance Previous research highlighted that people living with HIV(PLWHIV) are frequently excluded from clinical trials (CT) aimed at cancer treatment with immune checkpoint inhibitors (ICI), even if HIV is well controlled. Scientific societies and regulators have issued recommendations to correct this, and real-life evidence supports that the use of ICI in PLWHIV appears to be safe. There is no recent data on whether this trend has changed.
Aim and Objectives To determine whether HIV infection is an exclusion criterion in oncohaematological CT involving ICI available at our centre.