THE ROLE OF THE CLINICAL PHARMACIST IN THE SCREENING OF CANDIDATES FOR ONCOHAEMATOLOGICAL CLINICAL TRIALS

Background and importance:
Over the last decade the number of clinical trials (CTs) has increased exponentially worldwide as well as their complexity. The identification of possible interactions of the concomitant medication with the investigational drug is a key point to avoid bias in the study result, and to ensure patient safety. The pharmacist, as a member of the investigational team, may also be involved in screening / randomization of the subjects.

Aim and objectives:
To review the concomitant medication of patients who are candidates to start a CT in order to detect possible interactions.

Materials and methods:
Descriptive study developed in a tertiary university hospital: 1 year period (September 2020 - August 2021).

Included: All patients who were candidates to participate in an oncohematology clinical trial (CT) that included an oral investigational drug

Information on pharmacological treatment was obtained through a clinical interview conducted in the pharmaceutical care consultation or by telephone.

The inclusion/exclusion criteria related to concomitant prohibited / authorized medication described in the protocol of each trial were applied.

Collected: ✓ Sex ✓ Diagnosis ✓ Concomitant medication ✓ Pharmaceutical interventions ✓ Type of intervention ✓ How many of patients were taking alternative medicine products ✓ Number of screening failures

Results:
A total of 410 patients (53.90% women) were interviewed.

Interventions were performed in 155/410 (37.80%) patients.

Most of these (69.03%) were for suspension of treatment not authorized by protocol.

The 26.10% of the patients were taking alternative therapy at the time of screening.

Finally 20.49% were screening failure.

% of patients according to the diagnosis:

- Lung: 17.32%
- Genitourinary: 16.68%
- Neuroendocrine: 16.10%
- Breast: 14.88%
- Hematology: 8.78%
- Others: 26.09%

A total of 2262 drugs were reconciled.

The median of which they took per patient (range) was 5 (0-16).

Conclusion and relevance:
The results of our study show that approximately 4 out of 10 patients require at least one change in their usual treatment. The involvement of the pharmacist in the assessment of interactions may play a central role in the research process, which can directly influence the inclusion of a patient in a clinical trial.