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DESCRIPTIVE ANALYSIS OF ACTIVE CLINICAL TRIALS MANAGED IN A PHARMACY DEPARTMENT OF A TERTIARY HOSPITAL

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Background

Clinical trials (CT) lead to the development of new drugs and new indications for existing ones. The countries that have among their priorities participate in a large number of CT and of high quality ensure the best treatments for their patients, the best development for their scientists, institutions and health centers and,finally, additional resources from them for the health sector. It is important to know the design of clinical trials to interpret and evaluate the results when applying them to clinical practice.

Purpose

To characterise the main design aspects of CT managed in the pharmacy department of a tertiary hospital with an endowment of 710 beds.

Material and methods

This was a retrospective descriptive study of CT that were iniciated between 1 January 2016 and 30 September 2017. For each, we collected the phase of the CT, design (randomised/nonrandomised, blinded or unblinded, controlled/ uncontrolled) and the automation handling of the CT samples through the Interactive Web Response System (IWRS). In addition, the type of promoter responsible for the development of the CT, clinical departments involved and the international or national scope of the CT were studied. Information was obtained through the computer application PKensayos® and from documentation corresponding to each CT.

Results

In the studied period, 117 CT were initiated (66 in 2016 and 51 in the study period of 2017). Of these, 74 were phase III, 21 phase II, 11 phase I, 6 phase IV and in 5 studies two phases were combined. In terms of design, 79.5% were randomised, 55.6% were open label (the remainder were double blind), 78.6% were controlled (40.2% were placebo controlled). For 84.6% of CT, sample management was controlled automatically through IWRS. In 12% of the CT, the sponsor was an independent industry research entity. Clinical departments involved were: oncology 44.4%, endocrinology 12.8%, cardiology 12%, haematology 10.2%, digestive 8.5%, dermatology 4.3 %, pneumology 3.4 % and others 4.4%. Only 7.7% were national CT.

Conclusion

The predominant type was a phase III randomised, open, controlled with placebo, international, oncology trial. There was considerable informatisation (IWRS), and industry was responsible for the development of CT in most cases.

References and/or Acknowledgements

None.