

Inclusion of pharmacogenetics-studies, patient-reported outcomes and cost measures in clinical trials; variables added in recent years.- CPC-072

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Background

Pharmacogenetic-studies analyzed the variability of drug-response; patient-reported outcome (PRO) measures complement traditional measures. Pharmacoeconomic-studies permit us to know what the efficiency of different therapeutic alternatives is.

Purpose

To evaluate the use of PRO-measures, including health-related quality of life questionnaires (HRQoLQ), and the frequency of inclusion of pharmacogenetics-studies and economic variables in the design of clinical trials (CT) and observational studies (ST). For CT, also the quality study design was measured

Materials and Methods

Observational study of CT and ST approved by a Clinical Research Ethics Committee (actives between Jan/2008-May/2012). Recorded information:

- Medical specialty,
- Pathology,
- Methodological quality (Jadad scale:0-5),
- Inclusion of PRO,
- HRQoLQ,
- Pharmacogenetics-studies (existence/absence of collections of human biological samples) and
- Economic variables (use of sanitary resources and/or indirect costs defined as the number of days lost due to sick leave of patients and caregivers).

Information was systematically collected by 2 reviewers and by a third one when discrepancies appeared.

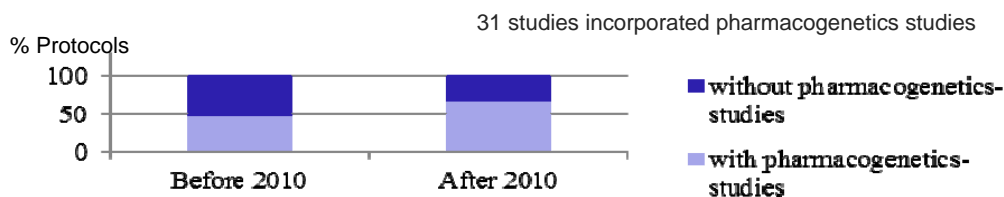
Results:

- The average quality score was 3,04 (Jadad scale).
- Analysis by area showed PRO-measures were most commonly studied in: endocrinology, neurology, digestive-diseases and cardiology.

Patient Reported Outcomes, PRO

	Clinical trials	Observational studies
Protocols (total number)	79	15
Protocols with PRO measures	44	7
Protocols with HRQoL Questionnaires	38	6

Pharmacogenetics studies



In the 50% of the pharmacogenetics-studies were programmed the storage of human biological collections in biobanks with the objective to get studies about drugs-responses according to the genetic endowment.

Economic variables

Twenty (25%) CT and two(18.2%) ST included economic variables

CONCLUSIONS

- The economic variables in CT and ST evaluated was low.
- More than half of protocols have included PRO-measures, reflecting the importance of these parameters.
- The greater pharmacogenetic knowledge has produced a higher inclusion of these studies in more recent CT.
- The average quality for the CT exceeded the value 3, indicating that studies analyzed doesn't have a low quality.