

Evolution of oncohaematological 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 trend in oncohaematology 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.

AIM AND OBJECTIVES

To describe and compare the characteristics of oncohaematology clinical trials opened in a tertiary hospital in 2016 and 2021.

MATERIALS 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 χ^2 . Results were deemed statistically significant at $p < 0.05$.

RESULTS

2016

vs.

2021

89	Interventional clinical trials started	71
93.6%	Main service: Medical Oncology	83.1%
22.5%	Largest number of trials initiated: Breast cancer	19.7%
82%	Industry-sponsored clinical trials, with an increase over time ($p=0.019$)	94.4%
58.4%	<i>Studies initiated:</i>	54.9%
89.6%	controlled	66.2%
76.7%	randomised	67.1%
	open-label	

with no statistically significant differences between 2016 and 2021

- An increase in the number of phase 3 clinical trials was observed (37.0 vs 54.93%; $p=0.017$), with a predominance of open-label design (54.55% vs 51.28%; $p>0.05$) and the use of surrogate endpoints as primary outcomes (54.5 vs 69.2%).
- **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.

