Why is it difficult to enrol patients in clinical cancer research?

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Abstract

Patient recruitments are a crucial part of clinical research, especially in the medical oncology field. Despite its significance, 2-3% of patients with cancer participate in clinical trials. Beyond the bureaucratic and financial barriers in most trials, the recruitment can be directly impacted by the study design, referrals and patient beliefs. Therefore, this study points out the difficulties related to the process of patient recruitments in oncology, followed by options that contribute to their improvement.

Keywords: Medical oncology; Clinical trials; Patient recruitments; Referrals; Research; Cancer patients.

1. Introduction

Advances in oncology directly depend on clinical research. In the past decade, the focus has been on the drug efficacy along with a better toxicity profile. [1] At present, clinical trial designs have become considerably more complex, allowing more personalized treatment. This could potentially avoid unnecessary exposure to patients who are less likely to respond to a specific therapy. [2]

Despite its significance, less than 3% of patients with cancer participate in clinical trials. [3] Beyond the bureaucratic and financial barriers in most trials, the recruitment can be directly impacted by some factors as the study design, referrals and patients’ beliefs. [4,5,6] The relevant factors that make it difficult for patient enrolment and some options to improve them are summarized in Table 1.

In order to avoid bias, study designs focus on diminishing the interference of confounder factors by methodically considering inclusion and exclusion criteria. On the one hand, this method often allows a clear interpretation of the study results without considering bias, which is virtually not possible. On the other hand, the real-world scenario is not a controlled environment. This impairs the generalization of clinical trials and the outcomes are frequently worse when compared with those of clinical practice. Additionally, a considerable number of trials do not reach the recruitment target and they are finalized prematurely. On occasion, this happens without the capability to test the objectives proposed previously in the study.

Strategically, clinical research should be seen as a complementary activity to clinical practice. This could diminish the workload of the teams in clinics as the research team is taking over patient care. As a result of this, it is possible to offer
patients other treatment options. The technology of pre-clinical models and contemporaneous study designs allows for a more reliable drug benefit and toxicity prediction, which is the actual aim of what researchers do and patients seek.

Table 1 Factors related to poor recruitment in cancer clinical trials.

<table>
<thead>
<tr>
<th>Related Factor</th>
<th>How to improve</th>
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<tbody>
<tr>
<td><strong>Study-related</strong></td>
<td></td>
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| Restricted inclusion (lines of treatment) and exclusion criteria (adverse events) | Consider broader inclusion criteria  
More comprehensive exclusion criteria  
Control comorbidities on study arms |
| Some comorbidities are excluded | |
| **Referrals-related** | |
| High workload impair discussion about research | Schedule time to discuss research  
Protocol presentation to referral teams  
Easier referral procedure (e-mail)  
Improve discussion during scientific events  
Less bureaucracy, allowing the creation of new research units in less central geographic regions. |
| Major focus on standard therapy | |
| Increased work to refer patients | |
| Studies are scarce in most cancer populations | |
| Fewer research units depending on the geographic area | |
| **Patient-related** | |
| Lack of trust and fear about what is done in clinical research | |
| Hesitation when using experimental drugs | |
| Wasting time by receiving a placebo | |
| High financial costs due to frequent visits to the study centre | |
| **Conclusion** | |

Therefore, knowing these barriers is the first step to overcome them. Those recommendations should be performed by individualizing the needs of every institution with a focus on patient preferences.

**Compliance with ethical standards**

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**Disclosure of conflict of interest**

All of the authors declare they have no conflict of interest, financial or otherwise.

**References**


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