

Expectations may not match reality among cancer patients in some early phase clinical trials

October 28 2016

In a study of cancer patients considering whether they should participate in phase I clinical trials, a high percentage were willing to participate after discussions with clinical staff, but nearly half thought that their tumors would shrink, which is much higher than what is realistically achieved. Published early online in *Cancer*, a peer-reviewed journal of the American Cancer Society, the findings demonstrate the challenges facing patients and healthcare professionals during their interactions in phase I studies.

Phase I trials are designed to assess the potential of investigational treatments that have never before been tested in humans. The trials, which are often restricted to patients with advanced disease that has not responded to standard therapy, start with conservatively low doses of a drug or other therapy and escalate until a recommended dose for a phase II trial is established. Typical response rates of phase I cancer trials range from four percent to 20 percent, and enrolled patients survive for a median of six months.

Ethically, healthcare professionals must ensure that patients are well informed about the likelihood of risks and benefits of phase I trials, and it is important to determine how effectively they're relaying such information. Led by Udai Banerji, MD, PhD, a UK team at The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research explored patients' motivations for considering phase I trials and assessed

their expectations both before and after they consulted with clinicians.

For the study, 396 patients who were considering participation in a phase I clinical trial completed questionnaires prior to being seen, and 301 completed an abbreviated follow-up questionnaire after consultation with clinicians.

When asked about the potential personal benefit of participating, 43 percent predicted tumor shrinkage in the initial questionnaire. After consultation, this increased to 47 percent. Thus current methods of communication did not lessen patients' pre-consultation expectations of benefit. Overall, patients were keen to consider trials, with 72 percent of pre- and 84 percent of post-clinic patients willing to enroll.

"There is a positive message in this, which is that 84 percent of patients are willing to participate in [phase](#) I oncology studies after a discussion with clinical and nursing staff who lay out the conservative estimates of benefit and requirements of hospital visits. This is good for current and future patients and cancer medicine in general," said Dr. Banerji. He added, "the high percentage of [patients](#) expecting their tumors to shrink was a sobering finding. This creates a challenge for [healthcare professionals](#) to manage expectations but to do so without being patronizing or dismissing human hope." The results also point to the need to improve patient information and consent forms.

More information: Saoirse O. Dolly et al, A study of motivations and expectations of patients seen in phase 1 oncology clinics, *Cancer* (2016). [DOI: 10.1002/cncr.30235](https://doi.org/10.1002/cncr.30235)

Provided by Wiley

Citation: Expectations may not match reality among cancer patients in some early phase clinical trials (2016, October 28) retrieved 25 April 2024 from

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