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Press release

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Research results
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Treatment no better in clinical trials

Patients taking part in clinical trials do not receive better treatment than other patients. This is the conclusion of a new study led from Uppsala University and published in peer-reviewed journal BMC Cancer, which confirms the results of an earlier study from 2004.

"There is a common belief among both healthcare professionals and patients that those taking part in clinical trials have better outcomes; however, we are unable to find any quality evidence that this is the case," says Tove Godskesen, associate researcher at Uppsala University's Centre for Research Ethics & Bioethics (CRB) and leader of the study.

If the best treatment for cancer patients is provided within the framework of clinical studies, then all patients should be encouraged to participate as, if such is the case, then the standard therapy is by definition only second best. Against this background, Jeffrey M Peppercorn, associate professor at Harvard Medical School, and his colleagues conducted a study that was published in The Lancet in 2004 (Peppercorn JM, Weeks JC, Cook EF, Joffe S: Comparison of outcomes in cancer patients treated within and outside clinical trials: conceptual framework and structured review. Lancet 2004, 363(9405):263-270. https://www.ncbi.nlm.nih.gov/pubmed/14751698).

Having asserted that there is a widespread opinion within oncology that patients with cancer who enrol in clinical trials have better outcomes than those who do not enrol, they conducted a comprehensive literature search to identify studies that compared outcomes between these groups. Their conclusion was that there are insufficient data to conclude that such a trial effect exists.

Given the rapid development of cancer treatment and the use of targeted therapy and immunotherapy, researchers were keen to repeat this study. This has now been done in a collaboration between Uppsala University, Rigshospitalet – Copenhagen University Hospital, Karolinska Institutet, Oslo University Hospital and Ersta Sköndal Bräcke University College. A total of 57 doctors and nurses working in oncology and haematology in Denmark and Sweden were interviewed to assess whether they were of the opinion that clinical studies offered the best treatment. A systematic literature review was also conducted to establish whether there is any basis for the contention that patients enrolled in clinical studies receive the best treatment.

"The interviews demonstrated that many doctors and nurses do indeed believe that it is better for patients to participate in clinical trials; however, we found no high-quality support in the literature review for the idea that participation provides better outcomes than standard care. So, our new results are in line with the study conducted by JM Peppercorn in 2004," says Zandra Engelbak Nielsen of Rigshospitalet, first author of the study.

In addition to direct effects, it might be expected that participation in a clinical study would have indirect positive effects, such as the patient receiving better all-round care – perhaps with more frequent follow-ups, sample-taking or appointments with research nurses. In this regard the researchers contend that, as the impact of such indirect effects depends on the specific circumstances and preferences of the individual patient, it is impossible to draw general conclusions as to whether treatment in clinical trials is better. To do so would be misleading, write the researchers.

“Clinical trials are important and a fundamental prerequisite for developing new, effective and safe cancer treatments. Given their well-developed healthcare sector, the Nordics should be conducting far more studies than is currently the case. One prerequisite for conducting clinical trials with high ethical standards in accordance with the Declaration of Helsinki is to provide factual information,” says Godskesen.

Instead, the emphasis should be on informing patients that those who volunteer for trials should do so out of the altruistic desire to contribute to advancing knowledge and for the potential benefit of future patients.

“This is where the media and pharmaceutical industry need to take their share of responsibility. Often, small steps in the right direction in a trial are presented as a major breakthrough, which is problematic. Clinical studies are complex and patients who are asked to participate have to trust what they are told by healthcare professionals. Both the welfare of individual patients and public confidence in healthcare are at stake,” says Engelbak Nielsen.

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