Patient satisfaction a priority in drug research

Professor Sirpa Leppä conducts clinical trials with lymphoma drugs. These trials help to improve treatment practices, cure patients and save a surprising amount in medical costs.

Every year, approximately 29,000 Finns are diagnosed with cancer, including 1,400 with lymphoma. Professor Sirpa Leppä is busy developing pharmacotherapies for cancers. She is a head of department at the Helsinki University Central Hospital Cancer Center, and Professor of Oncology at the University of Helsinki.

Leppä has made a successful job of combining research with patient consultation. She spends three days a week at the Cancer Center consulting lymphoma patients, most of whom take part in clinical trials. The rest of the week is spent conducting her own laboratory research, and performing the administrative duties of a professor and head of department.

“I try to find a balance between research work commissioned by pharmaceutical companies and investigator-initiated research,” Leppä explains. “Being a professor is great, because it allows me more freedom to decide how I use my time.”

Despite this, she often works long hours.

“Research has become more of a lifestyle than a job for me.”

Clinical trials not much different from a doctor's everyday work

Leppä is currently the Finnish lead scientist in three clinical trials for which patients are now being recruited. Two of these are Phase II trials and one a Phase III trial. According to Leppä, there are at least four trials either still in progress or where the patients are being monitored for effects. More than a hundred Finnish lymphoma patients participate in these trials. As all the trials are multinational, the total number of participants is even higher.

Trial participants visit Leppä regularly, but visits take no longer than any other patient consultation. The first takes an hour, and subsequent visits half an hour. Researchers and nurses complete all the paperwork at another time.

“In principle, this is not that much different from my ordinary work with patients. However, all research on drugs involves a great deal of 'invisible' work. Before a trial begins, we need to negotiate contracts and apply for permits and financing, and once the trial is in progress, we need to find suitable patients to recruit. Careful and systematic recording practices are essential in research. Adverse reactions and therapeutic efficacy are reported very carefully, and serious adverse drug reactions reported immediately.”

Drug trials create savings and a sense of security

Clinical trials generate significant savings for hospitals, as pharmaceutical companies provide the research drugs free of charge.

“I don't think people quite understand how much we save in drug costs by conducting research sponsored by the pharmaceutical industry,” Leppä points out. “Another major advantage is that we can use the drugs before they are granted marketing authorisation. This provides valuable information on the new drugs at an early stage.”

You might expect patients to be suspicious of taking any medicines that are not yet officially on the market. But according to Leppä, Finns generally take a positive attitude towards trials.

“It's very unusual for someone to decline participation in a trial. Participants are carefully monitored, which makes them feel safe and secure. Another major benefit is that patients see the same doctor throughout the trial. The follow-up period is usually five years.”

Fewer trials, more paperwork

While patient recruitment is no problem; the difficulty lies in attracting new drug trials to Finland. Sirpa Leppä is concerned over Finland's treatment in the selection process.

“We could conduct more research into new and significant biological lymphoma drugs, but we have not been offered as many trials in recent years. Conducting clinical trials is expensive in Finland, which may be a contributing factor. Finland is also a small country. Even though we have a good reputation, we are unable to recruit patient volumes on the same scale as bigger countries.”

This problem could be solved through Nordic cooperation.

“Finland should not be treated as an individual unit, but rather as part of the Nordic countries. We have a good network in lymphoma research, and considering the total population in all Nordic countries, combined with the high motivation of scientists and patients, we can easily compete with bigger countries in recruitment volumes.”

For the time being, however, a separate permit is required for trials in each Nordic country. In Finland, permit applications are submitted to Fimea, with whom Leppä is frequently in contact. As the lead scientist, she submits permit applications to Fimea for investigator-initiated research work, and provides statements required of the person in charge of the trial on investor-initiated research and trials commissioned by the pharmaceutical industry.

Researchers spend a surprisingly large amount of time doing paperwork. Data forms for drug trials are now in electronic format, but according to Leppä this has increased rather than decreased the amount of work and complexity, as the electronic forms sometimes require unnecessary minute details.

In addition to these reporting duties, Leppä is also responsible for negotiating the employment contracts of her research team members. Research nurses are hired from the Clinical Research Institute HUCH on a project basis.

“It's a real shame that excellent research nurses are only hired for a fixed period. Sometimes the lack of dedicated nurses can even obstruct a trial,” says Leppä.

Leppä's dream is to employ nurses at the medical examination unit permanently.

Grateful patients are the best reward

Despite all the red tape and lack of resources, Leppä sees her work as a calling.

“Improving clinical outcomes is my mission in life. Over the years, I have had the privilege of witnessing major improvements in treatments and higher survival rates in patients.”

Ten years ago, about half the patients diagnosed with an aggressive form of lymphoma were cured. Today, this is 70–80%. Research results are put into practice very quickly; the Cancer Center updates its own care recommendations annually, or more frequently if necessary. Similarly, national groups of cancer specialists, or tumour research groups, have their own care recommendations which the members update regularly. Significant changes are reported in scientific conferences and publications.

For Leppä, making new discoveries and observations is very rewarding, especially when you can share the experience with another researcher. Nevertheless, having her own article published in a scientific magazine is not the chief highlight for Leppä.

“What I appreciate most is patients coming up to me and thanking me for giving them good treatment,” she says.

In her role as a professor and tutor, she savours the moments when students finish their doctoral dissertations. She is currently tutoring five university students who are completing the doctoral programme. Her research group also includes four postdoctoral researchers.

Laboratory research supports practice

In her current investigator-initiated research, Sirpa Leppä aims to establish the order in which cancer drugs should be given to patients with aggressive lymphoma. Areas of future interest include more personalised pharmacotherapies for each cancer patient to find optimal treatments for the patient's disease.

“Developing a medicinal treatment for lymphoma goes in circles. If a specific treatment is no help to a patient, we must go back to the laboratory and figure out why that happened.”

Leppä's research group works at the Helsinki University Central Hospital Cancer Center and at Biomedicum Helsinki, the Genome Scale Biology Research Programme of the University of Helsinki. In addition to research scientists, her group includes a laboratory nurse and two research nurses. Researchers use molecular biology research approaches to establish, among others, the prognostic factors for lymphomas. This provides a better understanding of the clinical behaviour of various lymphoma subtypes, enabling more effectively targeted pharmacotherapies.

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NICE TO KNOW

SIRPA LEPPÄ

Born 1966

MD 1991, DMedSc 1994, docent of cancer biology 2004, specialist in oncology and radiation therapy 2004, docent of clinical oncology 2009.

Currently head of department at the Helsinki University Central Hospital Cancer Center, and a Professor of Oncology at the University of Helsinki.

She is also the leader of a research group in Biomedicum's Genome Scale Biology Research Programme, and the head of the aggressive lymphoma working group in a Nordic lymphoma research group.

NICE TO KNOW

LYMPHOMAS

A group of diseases with very dissimilar clinical presentation, treatment and prognosis.

Can be divided into two main groups: Hodgkin and non-Hodgkin lymphomas.

In 2012, 155 Finnish people were diagnosed with Hodgkin lymphoma and 1,306 with non-Hodgkin lymphomas (www.cancer.fi/syoparekisteri).

The most common non-Hodgkin lymphomas are diffuse large B-cell, follicular, and lymphocytic lymphoma (a type of chronic lymphocytic leukemia).

Most common treatments include chemotherapy, which can be combined with radiation therapy.

Diffuse large B-cell lymphoma is treated with a combination chemotherapy including anti-CD20 antibody by which approximately 70% of the patients are cured completely.

More information: Riihijärvi S, Leppä S. Diffuusin suurisoluisen B-solulymfooman ennustekijät ja hoito. Duodecim 2014; 130: 2181–9 (in Finnish).