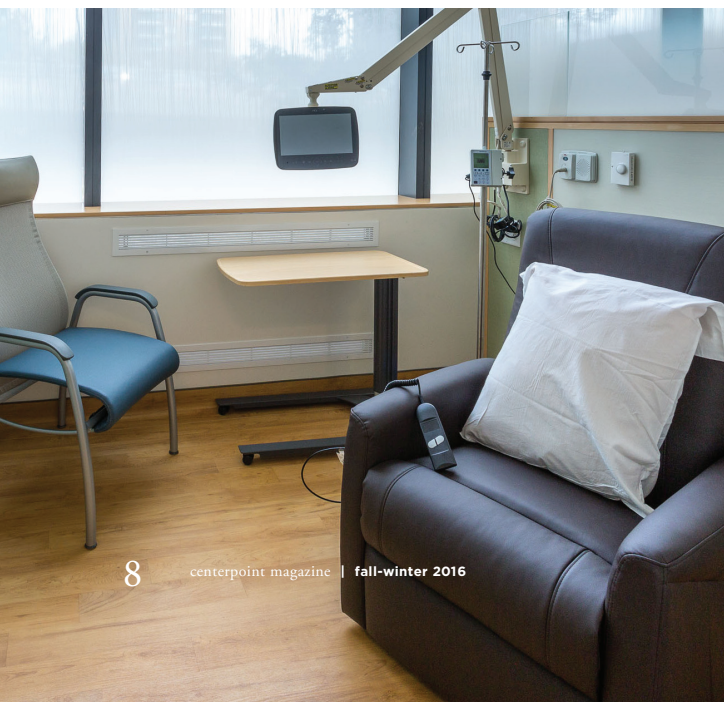




Dedicated Space for PHASE I CLINICAL TRIALS



Steve Kemper writer Carl Kaufman photographer

In keeping with its mission to provide cancer patients with the most innovative treatments available, Yale Cancer Center has greatly increased the number of phase I clinical trials that investigate novel therapies. In September, this expansion led to the opening of a new Phase I Clinical Trial Infusion Center at Smilow Cancer Hospital. It is the only such center in Connecticut.

Many patients participate in phase I trials because their cancer has not responded to standard treatment and they are looking for something that might work. The new therapies tested in clinical trials offer these patients another option as well as hope.

Phase I trials have unique requirements that are hard to

neuroendocrine cancers. “We’re doing a lot of sophisticated trials on both rare and common solid tumors,” said Dr. LoRusso.

She adds that having a space dedicated to phase I infusions is advantageous both to clinicians and to patients. Physicians at an academic center such as Yale not only want to treat patients, but to develop novel therapies and bring new science into the clinic. The new infusion center helps encourage that, Dr. LoRusso explained. Physicians also feel reassured that this space reserved for cutting-edge treatments is supported by specially-trained staff.

The advantages for patients are also significant. Many patients join phase I trials because their cancer has progressed beyond conventional treatment. They may already be on narcotics



“There’s more complexity to phase I trials, and the monitoring is much more exact and intensive. As a result, it’s best if phase I trials take place in a dedicated infusion center with its own trained and skilled staff.”



satisfy in a typical infusion center, says Patricia LoRusso, DO, Professor of Medicine (Medical Oncology) and Associate Director of Innovative Medicine at Yale Cancer Center. In an infusion center that provides conventional chemotherapy, a nurse typically takes vital signs, hooks up the patient to a hanging bag filled with a well-known chemical agent, monitors the infusion, then disconnects the IV so that the patient can go home.

By contrast, a phase I trial contains a lot more unknowns, starting with the drug being infused. “Maybe the drug has never been given before,” Dr. LoRusso explained, “or maybe it’s only been given a few times to a few people. You don’t know if the patient will have a reaction, because it’s all new.”

For that reason, the medical staff must do special labs and tests before, during, and after the infusion, as well as check vital signs at specific points throughout. “The level of skilled nursing and skilled care is different,” said Dr. LoRusso. “There’s more complexity, and the monitoring is much more exact and intensive.” As a result, she adds, it’s best if phase I trials take place in a dedicated infusion center with its own trained and skilled staff.

At the moment, the specially-trained staff at the center includes nurses and medical assistants as well as the four clinicians running the trials, which currently number almost 40. The trials encompass targeted drugs, monoclonal antibodies, and immunotherapies. Investigators at Yale initiated some trials; pharmaceutical companies sponsor others. All are aimed at solid tumor cancers, including breast, colon, ovarian, pancreatic, and

or other drugs to deal with the effects of their disease.

“So it can be confusing and complicated to them if they don’t know where they’re going for each visit, or if the environment changes,” Dr. LoRusso said. “When they know they’re going to the same place every time, it’s much easier for them. They become familiar with the staff and feel much more comfortable and safe because everything is contained.”

The new unit is already handling about 650 patient visits per month, which includes appointments for lab work and meetings with physicians as well as infusion treatments. The number of visits is expected to grow rapidly as more phase I trials are available.

The unit has been carefully designed for efficiency and comfort. Eleven walled infusion stalls are built around an open nursing station, allowing the staff to see all the patients while also giving each patient a private space. There is also a clinic where physicians examine patients, and an area where patients or their families can get snacks and relax. “The unit is beautiful,” Dr. LoRusso said.

All of this—the innovative therapies, the dedicated space and staff, the thoughtful design—is aimed at providing relief and hope to patients, many of whom are in advanced stages of cancer. “Having an infusion center devoted to phase I trials gives them additional treatment options, which they would not otherwise have,” said Dr. LoRusso, “so I think it offers them hope.”

As more clinical trials open at the center, there will be more hope for more patients. ↻