NEPHROLOGY NEWS & ISSUES

Home

Preparing for the Wearable Artificial Kidney's first human clinical trial in the US

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The Wearable Artificial Kidney (WAK), Invented by nephrologist Victor Gura, MD, FASN, from the David Geffen School of Medicine at UCLA, has been involved in laboratory and clinical testing since 2001 by medical clinicians, bio medical engineers, and other medical device researchers. The present prototype of the WAK is a 10-pound device, powered by nine volt batteries and worn around the waist. It is manufactured by Blood Purification Technologies, based in Beverly Hills, Calif.

“Recently the FDA approved the first WAK human trial in the United States,” Gura said. “The clinical trial will require rigorous testing modalities required by federal regulators. The FDA has been very cooperative and supportive to us and our goals, and provided key guidance through the approval process.”

Study Aims and expectations
The aim of this trial, and subsequent trials, is to bring WAK to the public forefront and use it for commercial purposes to improve the lives of hemodialysis patients.

“Human clinical trials conducted in Italy and England have already been successfully concluded,” said Gura. “So, if WAK continues to perform this well during clinical trials in the United States it will become a game changer. We hope to give patients a better quality of life. They won’t need to be tethered to large static dialysis machines, and hopefully the trials will prove WAK can remove as much physiologic fluid and salt from the body as kidneys do.”

When body fluids are at normal levels, health conditions like pulmonary edema and hypertension will most likely be alleviated or completely eliminated. And because WAK wearers would receive continuous hemodialysis, patients might not require dietary and fluid restrictions or need dietary binders to control phosphorus buildup. Currently, nephrologists have to prescribe numerous medications for these patients in an effort to assist the body to remain in homeostasis. With the use of the WAK, some medications may be medically discontinued.

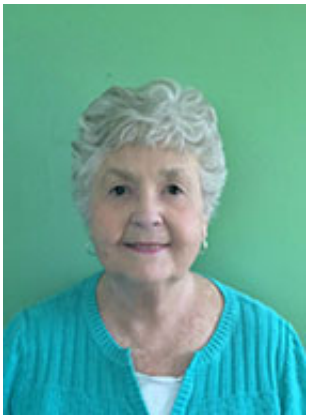
“WAK technology is closer to the way kidney transplants function,” Gura said. “Hopefully, the first United States clinical trial will help to demonstrated thatthe WAK device produces many positive patient outcomes.”

Future aims
According to Gura, the current WAK prototype will become smaller, lighter and easier to wear. Eventually, if

all works out well with the trial results, patients may be able to pick up WAK belts at their local dialysis centers, Gura said.

WAK funding issues

The research and development of the WAK medical device will require large sums of money. According to Gura, donations have come from private individuals that are kidney patients or have friends or family members on dialysis, not from corporations.



Ms. Fox Rose is an author of four non-fiction, nursing related books. Her work has been published in national nursing and health care publications, including numerous articles that have appeared in Advance for Nurses Magazine/webpage, Healthcare Traveler Magazine/Webpage. A generalist, she's been published in Woman's World magazine and in local and regional newspapers and publications.