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1510 H Street NW • Suite 800 • Washington, DC 20005
p 202.640.4660 • F 202.637.9793 • www.asn-online.org

Press Release

Contacts: **Tracy Hampton • (312) 339-9067 • thampton@nasw.org**
Christine Feheley • (202) 640-4638 • cfeheley@asn-online.org

INVESTIGATORS INCORPORATE RANDOMIZED TRIAL WITHIN DIALYSIS CARE DELIVERY

Trial examines potential benefit of longer dialysis sessions.

Highlights

- The Time to Reduce Mortality in ESRD (TiME) trial was a large pragmatic trial demonstration project designed to determine the benefits of hemodialysis sessions that are longer than many patients currently receive.
- The trial was conducted through a partnership between academic investigators and 2 large dialysis provider organizations using a highly centralized implementation approach.
- Although the trial accomplished most of its demonstration project objectives, uptake of the intervention was insufficient to determine whether longer sessions improve outcomes.

Washington, DC (April 18, 2019) — A recent clinical trial fully embedded into the routine delivery of care at dialysis facilities sought to determine if hemodialysis sessions that are longer than many patients in the United States currently receive can improve patients' health. Although the trial accomplished most of its objectives, uptake of the intervention was insufficient to determine whether longer sessions are beneficial. The findings, which appear in an upcoming issue of *JASN*, indicate that embedding trials into dialysis care will require more effective strategies for engaging clinicians and patients.

The trial's investigators had 2 goals: to develop approaches for embedding large randomized trials into the routine delivery of clinical care, and to determine whether patients benefit from hemodialysis sessions that are longer than usual. In the Time to Reduce Mortality in ESRD (TiME) trial, 266 dialysis facilities randomized to the intervention adopted a default hemodialysis session duration of at least 4.25 hours for new dialysis patients; those randomized to usual care had no trial-specified approach to duration. Trial implementation was highly centralized, with no on-site research personnel and complete reliance on clinically acquired data.

The team demonstrated that a trial embedded into clinical care delivery with no on-site research personnel could efficiently enroll a large number of participants using an opt-out approach to informed consent. (The trial enrolled 7,035 patients.) The trial was also able

to obtain useful treatment and outcomes data from hundreds of medical facilities and monitor trial conduct and safety through a centralized approach.

The trial was discontinued at a median follow-up of 1.1 years because of an inadequate between-group difference in session duration. Average session duration was 216 minutes for the intervention group and 207 minutes for the usual care group. Investigators found no reduction in mortality or hospitalization rates for the intervention vs. usual care.

“There is a pressing need for data from randomized trials to guide clinical practice in dialysis,” said lead author Laura M. Dember, MD (University of Pennsylvania Perelman School of Medicine). “Pragmatic trials embedded in clinical care delivery have tremendous potential for efficiently producing evidence that is highly generalizable to the non-research setting; however, experience with this approach is limited. The TiME trial provides an important foundation for future pragmatic trials in dialysis as well as in other settings.”

Study co-authors include Eduardo Lacson, Jr, MD, MPH, Steven M. Brunelli, MD, MSCE, Jesse Y. Hsu, PhD, Alfred K. Cheung, MD, John T. Daugirdas, MD, Tom Greene, PhD, Csaba P. Kovesdy, MD, Dana C. Miskulin, MD, MS, Ravi I. Thadhani, MD, MPH, Wolfgang Winkelmayer, MD, DSc, Susan S. Ellenberg, PhD, Denise Cifelli, MS, Rosemary Madigan, MS, MPH, Amy Young, BA, Michael Angeletti, MS, RD, Rebecca L. Wingard, RN, MSN, Christina Kahn, BS, CCRP, Allen R. Nissenson, MD, Franklin W. Maddux, MD, Kevin C. Abbott, MS, MPH, and J. Richard Landis, PhD.

Disclosures: L.M. Dember receives compensation from the National Kidney Foundation as a Deputy Editor for the American Journal of Kidney Diseases, is a member of a Data Monitoring Committee for Proteon Therapeutics, and is a consultant to GlaxoSmithKline. E. Lacson, Jr. is currently employed by Dialysis Clinic, Inc., a not-for-profit dialysis provider, and was employed by Fresenius Medical Care North America during the planning and much of the conduct of the trial. S.M. Brunelli is employed by DaVita and his wife is employed by AstraZeneca. J.Y. Hsu receives compensation from the National Kidney Foundation as an editor for the American Journal of Kidney Diseases. A.K. Cheung is a consultant for Boehringer-Ingelheim and contributor to UptoDate. C.P. Kovesdy is a recipient of funding for a USRDS Special Study Section (U01DK102163). D.C. Misulin receives salary support for research activities from Dialysis Clinic, Inc. R.I. Thadhani is a consultant to Fresenius Medical Care North America. A. Young is employed by DaVita. M. Angeletti is employed by Fresenius Medical Care. R.L. Wingard is employed by and receives salary and stock options from Fresenius Medical Care. C. Kahn is employed by and owns stock in Fresenius Medical Care. A.R. Nissenson is employed by and receives salary and stock options from DaVita. F.W. Maddux is employed by and has equity shares in Fresenius Medical Care, serves on the following Board of Directors: Goldfinch Bio, Vifor Fresenius Medical Care Renal Pharma, Pacific Renal Care Foundation, and American National Bank & Trust (NASDAQ:AMNB). K.C. Abbott has equity in General Electric.

The article, entitled “The TiME Trial: A Fully Embedded, Cluster-Randomized, Pragmatic Trial of Hemodialysis Session Duration,” will appear online at http://jasn.asnjournals.org/ on April 18, 2019, doi: 10.1681/ASN.2018090945.

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Facebook: A recent clinical trial embedded into the routine delivery of care at dialysis facilities sought to determine if hemodialysis sessions that are longer than many patients currently receive can improve patients’ health. Although the trial accomplished many of its objectives, uptake of the intervention was insufficient to determine whether longer sessions are beneficial. The findings, which appear in the *Journal of the American Society of Nephrology*, indicate that embedding trials into dialysis care will require more effective strategies for engaging clinicians and patients.