

ISN Trial-List

July 2017



Once a month, the ISN-ACT (Advancing Clinical Trials) initiative team collects and publishes a list of important nephrology trials from the latest medical literature.

Dialysis

ISN Academy: [Dialysis](#)

Extended hours hemodialysis may not impact quality of life

A Trial of Extending Hemodialysis Hours and Quality of Life

Jardine, et al. *J Am Soc Nephrol.* 2017;28(6):1898-1911

The benefits of more intensive dialysis seen in observational studies have not been replicated in randomized trials. In the ACTIVE Dialysis trial Jardine, et al. randomized 200 participants in four countries to extended hours (≥ 24 hours per week) or standard hours (≤ 18 hours per week) and followed them for 12 months. The majority of participants in the treatment arm were on 8 hours thrice weekly. No difference in quality of life (as measured by EuroQol-5D) was observed at 12 months, although a small, but significant improvement in Short-Form 36 Physical Component Summary was seen (2.68 [95% CI, 0.39 to 4.97; $P=0.02$]). Mean phosphate and potassium were lower in the treatment group and hemoglobin was higher. The number of phosphate binders and antihypertensive medications was also lower in the treatment group. There was no difference in blood pressure and a 95-participant substudy showed no statistically significant improvement in left ventricular mass index. While these results do not suggest substantial benefits from extended hours dialysis over a 12 month period, the longer term impacts remain unclear and follow-up studies are awaited.

<http://jasn.asnjournals.org/content/early/2017/01/31/ASN.2015111225.abstract>

Anaemia, Iron and Trace Elements

ISN Academy: [Anaemia, Iron and Trace Elements](#)

Ferric citrate as a treatment for iron-deficiency anaemia in CKD

Effects of Ferric Citrate in Patients with Nondialysis-Dependent CKD and Iron Deficiency Anemia

Fishbane, et al. *J Am Soc Nephrol.* 2017;28(6):1851-1858

Ferric citrate was approved as a phosphate binder for patients on maintenance dialysis but its potential role in the management of anaemia and iron deficiency has been recognized. Fishbane, et al. randomized 233 patients with a mean eGFR of 28.7ml/min/1.73m² and iron deficiency anaemia in a double-blind placebo-controlled trial of oral ferric citrate. The mean number of tablets during the study was 5 per day in both groups. The primary outcome of a ≥ 1 g/dl [10g/l] rise in haemoglobin at any point during the 16 week trial period was achieved significantly more often with ferric citrate (52.1%) than with placebo (19.1%). Gastrointestinal adverse events were also more common in the treatment group (diarrhea, 20.5%; constipation, 18.8%; nausea, 11.1%; abdominal pain, 6.0%), although no statistical comparison with the placebo group was reported. Serum phosphate was also reduced by 0.21mg/dl [0.07mmol/l] in the treatment group. This study shows that oral ferric citrate may be effective in non-dialysis CKD patients but also suggests that tolerability may limit its use.

<http://jasn.asnjournals.org/content/early/2017/02/08/ASN.2016101053.full.pdf>

Maintaining liberal versus strict phosphate targets is possible in a trial setting

Two phosphate targets in End-stage renal disease Trial (TARGET): A Randomized Controlled Trial

Wald, et al. *Clin J Am Soc Nephrol.* 2017;12(6):965-973

Current recommendations are that serum phosphate be lowered 'toward normal' in CKD5D but the optimal level remains unknown. Wald, et al. report a pilot study assessing the feasibility of targeting a liberal (2.0-2.5mmol/l) or strict (0.75-1.5mmol/l) serum phosphate in a clinical trial setting. They randomized 104 participants receiving hemodialysis to liberal or strict phosphate control achieved using calcium carbonate dosed according to a nomogram and followed them for 26 weeks. They demonstrated that statistically significant separation between groups could be maintained over the duration of the trial with no significant difference in adverse events. This trial suggests that a long term study comparing the effect of different phosphate treatment targets on patient-centred outcomes is feasible and tolerable in the hemodialysis population.

<http://cjasn.asnjournals.org.ezproxy1.library.usyd.edu.au/content/12/6/965.full>
