Once a month, the ISN-ACT (Advancing Clinical Trials) team collects and publishes a list of latest randomized research from nephrologists all around the world. Each trial is reviewed in context and their risk of bias in seven key areas assessed.

Join the debate on Twitter by following @ISNeducation: Will these trials affect your practice? Are the results valid? How could the trials have been improved? What further studies are needed?

If you would like to suggest any trials for inclusion in future editions, please send suggestions to research@theisn.org.

### Contents

- **Polyhexanide similar to iodine for PD catheter exit site care** ................................................................. 1
- **Roxadustat may be effectively dosed three times per week or weekly** ..................................................... 1
- **CKD practice nurse and regular medical record audit does not affect progression of CKD in primary care** ........... 2
- **EPO post-transplant does not affect eGFR in pilot study** ................................................................................ 2
- **Lower tacrolimus dosing feasible in low-risk Asian transplant recipients** ....................................................... 2
- **Longer courses of prednisolone might lower healthcare costs but do not affect relapse rate in childhood nephrotic syndrome.** ........................................................................................................... 3
- **Perindopril-amlodipine equal to perindopril-indapamide in pilot BP lowering study in Sub-Saharan diabetics** ...... 3

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### ISN Academy: Peritoneal Dialysis

**Polyhexanide: an alternative to iodine for PD catheter exit site care?**

Effect of Local Polyhexanide Application in Preventing Exit-Site Infection and Peritonitis: A Randomized Controlled Trial


<table>
<thead>
<tr>
<th>Population</th>
<th>93 peritoneal dialysis patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention vs Comparator</td>
<td>Regular exit site application of polyhexanide vs. povidone-iodine</td>
</tr>
<tr>
<td>Time</td>
<td>12 months</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Rates of exit site infections (ESIs) were similar, with 3 ESIs in the polyhexanide group and 5 ESIs in the povidone-iodine group (0.06 episodes/patient-year vs. 0.12 episodes/patient-year; P=NS). Peritonitis rates were also similar, with 12 episodes with polyhexanide and 13 with povidone-iodine (0.26 episodes/patient-year vs. 0.32 episodes/patient-year, P=NS).</td>
</tr>
</tbody>
</table>

Polyhexanide appeared similarly effective to povidone-iodine for infection prophylaxis in patients on PD. However the small size and methodological limitations of this study mean these findings should be interpreted with caution.

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### ISN Academy: Anaemia, Iron and Trace elements, Chronic Kidney Disease

**Roxadustat may be effectively dosed three times per week or weekly**

Roxadustat Treatment of Chronic Kidney Disease-Associated Anemia in Japanese Patients Not on Dialysis: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Trial


| Population | 107 patients with non-dialysis dependent CKD and anemia |
**Intervention vs Comparator**

Roxadustat (thrice-weekly, variable dosing) vs. placebo

**Time** 24 weeks

**Outcomes**

Response rate (Hb > 100g/L or >10g/L above baseline) was 94% in the roxadustat group vs. 15% in the placebo group (P<0.001).

A subgroup of 56 participants who achieved Hb>110g/L on roxadustat were re-randomized to continue thrice-weekly dosing or to reduce to once-weekly dosing. Both approaches resulted in a mean Hb > 10g/L at week 24.

This study suggests that less frequent dosing of roxadustat is feasible, although the long-term safety of this approach is not yet known.

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**CKD practice nurse and regular medical record audit does not affect progression of CKD in primary care**

The Primary-Secondary Care Partnership to Improve Outcomes in Chronic Kidney Disease (PSP-CKD) Study: A Cluster Randomized Trial in Primary Care

**Population**

46 primary care practices

**Intervention vs Comparator**

CKD nurse-specialist support to review and improve CKD care plus biannual medical record audit of renal function, blood pressure and related parameters vs. unsupported provision of biannual audit data

**Time** 42 months

**Outcomes**

No difference in change in eGFR.

Coding accuracy improved. At most timepoints, patients in the intervention practices were more likely to achieve BP targets

Nurse supported CKD management in primary care did not protect renal function, but improvements in some aspects of care were noted.

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**EPO post-transplant does not affect eGFR in pilot study**

Treating Posttransplant Anemia With Erythropoietin Improves Quality of Life but Does Not Affect Progression of Chronic Kidney Disease

**Population**

55 patients 3-months post-renal transplant with hemoglobin 90-115g/L

**Intervention vs Comparator**

Epoetin-beta titrated to target 115-135g/L vs. no treatment

**Time** 2 years

**Outcomes**

No differences in eGFR, proteinuria or blood pressure

The authors report improvement in one of eight domains of SF-36 quality of life (vitality)

In this pilot study, two years of epoetin therapy following renal transplant did not affect decline in eGFR. The effect on quality of life is difficult to judge given the limitations of this study.

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**Lower tacrolimus dosing feasible in low-risk Asian transplant recipients**

Safety and Efficacy of Reduced Prolonged-release Tacrolimus Exposure in De Novo Kidney Transplantation: A Randomized, Open-label, Pilot Study in Asia-OPTIMIZE Study

**Population**

66 low immunological risk kidney transplant recipients; all received basiliximab induction, mycophenolate and corticosteroids, and tacrolimus targeted to 6-10ng/L weeks 1-4.

**Intervention vs Comparator**

Reduced dose prolonged-release (PR) tacrolimus [trough 4-6ng/L wk 4-12, then 3-5ng/L wk 12-52] vs. standard dose PR tacrolimus [trough 6-10 wk 4-52].

**Time** 52 weeks
Outcomes

No difference in primary outcome of eGFR at 52 weeks
No differences in acute rejection (4 vs. 3), de-novo DSA at 52 weeks (3 vs. 2 participants) or adverse events

In this small study, at 1 year post-transplant, reduced-dose prolonged-release tacrolimus was as effective as standard-dose in Asian kidney transplant recipients with low immunologic risk.

Longer courses of prednisolone might lower healthcare costs but do not affect relapse rate in childhood nephrotic syndrome.

Long term tapering versus standard prednisolone treatment for first episode of childhood nephrotic syndrome: phase III randomised controlled trial and economic evaluation. The PREDNOS trial
Webb et al. BMJ 2019;365:i1800

Population 237 children aged 1-14 with a first episode of steroid sensitive nephrotic syndrome

Intervention vs Comparator
16 weeks of prednisolone vs. 8 weeks of prednisolone

Time 24 months

Outcomes
No significant difference in time to first relapse (HR 0.87, 95% CI 0.65 to 1.17, P=0.28)
No difference in incidence of frequently relapsing nephrotic syndrome, steroid dependence or use of alternative immunosuppressive treatment. No difference in adverse event rates (17% extended course vs. 25% standard, P=0.13)

There was a cost saving in the longer tapering arm (difference -£1673, 95% CI -£3455 to £109)

Clinical outcomes appear similar between 8 and 16 week courses of corticosteroids for pediatric steroid responsive nephrotic syndrome. A cost benefit to the healthcare system was estimated for the longer treatment course, mainly due to reduced health care encounters over the follow up period.

Perindopril-amlodipine equal to perindopril-indapamide in pilot BP lowering study in Sub-Saharan diabetics

Short-term effects of perindopril-amlodipine vs perindopril-indapamide on blood pressure control in sub-Saharan type 2 diabetic individuals newly diagnosed for hypertension: A double-blinded randomised controlled trial

Population 30 type 2 diabetic participants with Grade I-II hypertension (treatment naïve)

Intervention vs Comparator
Perindopril 5mg-amlodipine 5mg vs. perindopril 5mg-indapamide 1.25mg

Time 6 weeks

Outcomes
No difference in BP lowering between two arms (24-hour SBP 144mmHg to 128mmHg [P=0.003] with perindopril/amlodipine vs. 145mmHg to 126mmHg with perindopril/indapamide [P=0.003])

No significant adverse events

This pilot study suggests perindopril-amlodipine and perindopril-indapamide are equally efficacious in a Sub-Saharan population. Although of insufficient size and duration to adequately assess adverse effects, this study may aid in the design of future trials in this population.