DIalysis Symptom COntrol Restless Legs Syndrome (DISCO-RLS) Trial

Population Health Research Institute
HEALTH THROUGH KNOWLEDGE

Can-SOLVE CKD Network

Strategy for Patient-Oriented Research
SPOR
Putting Patients First

1. BACKGROUND

•Restless legs syndrome (RLS) affects 30% of patients with kidney disease

•It is associated with difficulty sleeping and poor health related quality of life
•It is a top research priority for dialysis patients
•Typical medications used to treat RLS have unacceptable side effect profiles and adverse events at standard doses

Research question

What is the best way to treat restless legs syndrome in hemodialysis patients?

2. PROJECT GOAL

- To assess the safety and efficacy of low fixed dose medications (ropinirole and gabapentin) for the treatment of RLS in patients with end stage kidney disease requiring hemodialysis

3. PROJECT TEAM

- Role of **patient partners**:

1) Study design
acceptability and feasibility run-in period
generalizability of eligibility criteria
relevance and burden of outcomes
2) Informed consent form development
3) Patient information sheet development
4) Flipchart to enhance the informed consent process
(Study Within A Trial=SWAT)
5) Knowledge translation

Patient Partners:
Gwen Herrington
Lucy Delgado
Paul Duperron
Roger Hillier

Qualified Investigators:
Chris Rabbat
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Principal Investigators:
David Collister
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Project Team:
Project Manager: Jessica Tyrwhitt
Research Coordinator: Kayla Pohl
Statistician: Shun Fu Lee

4. WHAT IS THE STUDY DESIGN?

A) Eligibility Criteria

Inclusion

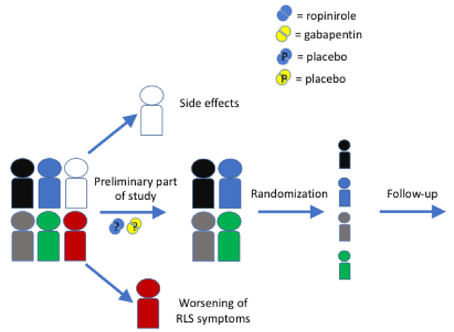
1) Age greater than or equal to 18 years
2) Has received at least 90 days of in-center HD at a frequency at least 3 times weekly
3) RLS defined by 2012 Revised IRLSSG Diagnostic Criteria and of moderate severity defined by an IRLS≥15 with symptoms more than 2 days per weeks
4) Provides informed consent

Exclusion

1) Hemoglobin<80g/L in the previous 4 weeks
2) Ferritin <50ng/ml in the previous 4 weeks
3) Intolerance to study medications
4) Change in medication to treat RLS in previous 4 weeks
5) Current or planned pregnancy
6) Planned kidney transplantation, travel or relocation in the next 6 months
7) Unable to complete RLS symptom and HRQOL measurements due to language barrier or cognitive impairment

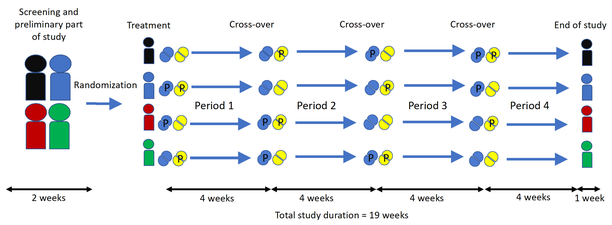
B) Run-in period

single blind
double placebo
2 weeks
Identification + exclusion
1) non-adherence
2) placebo response
3) Inability to tolerate placebo



C) 4 crossover periods

double blind
4 weeks each
gabapentin + ropinirole
gabapentin + placebo
ropinirole + placebo
placebo + placebo



Outcomes:
1º = change in IRLS
2º = change in RLS-6, PGI, EQ-5D-5L, adverse events

D) Sample size

N=80
9 centers across Canada

ClinicalTrials.gov

https://clinicaltrials.gov/ct2/show/NCT03806530

5. ACHIEVEMENTS/LESSONS LEARNED

- CNTN is a valuable setting to refine a protocol and get feedback from multiple stakeholders
- Screening for RLS can be successfully performed using preexisting patient outcome reporting measures e.g. ESAS, IRLS
- A SWAT can easily be embedded within a trial
- **Patient partners can effectively be utilized at every stage of a clinical trial to enhance its quality and feasibility**

CNTN|RCEN
Canadian Nephrology Trials Network
Réseau canadien d'essais cliniques en néphrologie

ORIGINAL ARTICLE
Screening questions for the diagnosis of restless legs syndrome in hemodialysis
ckj OXFORD *Clinical Kidney Journal*, 2018, 1–5
doi: 10.1093/ckj/sfy129
Original Article

TRIAL FORGE

6. PROJECT TIMELINE

Objective	2017				2018				2019				2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Prepartory Work																
Patient engagement	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Protocol development	■	■	■	■	■	■										
ICF development	■	■	■	■	■	■										
Flip chart development	■	■	■	■	■	■										
Treatment sourcing					■	■										
Database development					■	■										
Case report form development							■	■								
Regulatory approval							■	■								
CTO ethics approval							■	■								
SJHH Site Initiation									■	■						
Site initiations									■	■	■	■				
Trial Conduct																
Participant recruitment									■	■	■	■				
Treatment and follow-up									■	■	■	■	■			
Data cleaning and quality assurance									■	■	■	■	■	■		
Post Trial Work																
Analyses														■		
Manuscript preparation														■	■	
Knowledge translation planning															■	■
Knowledge translation activities															■	■

7. COMMENTS

yes, write here!!!

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@lastwalsh
@PHRIresearch

Ask to see our publication, informed consent form, patient information sheet and flipchart for patient recruitment