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
- Typical medications used to treat RLS have unacceptable side effect profiles and adverse events at standard doses

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: Patient Partners
  1) Study design
  2) Acceptability and feasibility run-in period
  3) Generalizability of eligibility criteria
  4) Informed consent form development
  5) Patient information sheet development
  6) Flipchart to enhance the informed consent process
  7) Knowledge translation

- Role: Project Manager
  1) Study design
  2) Acceptability and feasibility run-in period
  3) Generalizability of eligibility criteria
  4) Informed consent form development
  5) Patient information sheet development
  6) Flipchart to enhance the informed consent process
  7) Knowledge translation

Principal Investigators:
- David Collister
- Michael Walsh

Qualified Investigators:
- Chris Rabbat
- Ron Wald
- Karthik Tennankore
- Braden Manns
- Neesh Pannu
- Deb Zimmerman
- Francois Madore
- Annie-Claire Nadeau Fredette
- Navdeep Tangri

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 score of more than 15 with symptoms more than 2 days per week
4) Provides informed consent

Exclusion
1) Hemoglobin < 80 g/L in the previous 4 weeks
2) Ferritin < 50 ng/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 questionnaires 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

D) Sample size
- n=80
- 9 centers across Canada

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

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, RLS
- 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

6. PROJECT TIMELINE

7. COMMENTS

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

@turbo_dc
@lstatwalsh
@PHRiresearch