

## Progress Report: Sri Lanka Clinical Trials Registry

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SLCTR registration number: SLTCR/2019/008

Scientific title of trial: Protocol for a randomized double blind, placebo controlled, crossover trial of melatonin for treatment of sleep disorders in patients with cirrhosis

Date of commencement (enrolment of first participant): 2019-03-12

Progression: 6 months  1 year  2 years  3 years   
At completion

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### 1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

### 2. Current status

Recruitment status: pending/ recruiting/ **recruitment complete**/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 180

Number recruited and allocated/randomized: 71

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1: 41

Arm 2: 30

Losses/exclusions after allocation/randomization (please edit as relevant):

Arm 1: 11

Arm 2: 0

### 3. Trial output

Date of trial completion ("last patient, last visit"): 2019-06-01

Final sample size: 60 crossover

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Summary of Interim/Final data (if available):

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Abstract presentations of results at scientific meetings

*Note: please include a URL link or scanned copy of the abstract*

<b>Title of Abstract</b>	<b>Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).</b>

Publications

*Note: please include a URL link or scanned copy of the publication*

<b>Title of paper</b>	<b>Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)</b>

  
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Name and signature of Responsible Registrant/  
Principal Investigator

Date: 4/6/19