CLARITY

Controlled evaLuation of Angiotensin Receptor Blockers for COVID-19 respIraTorY disease

Issue 6 | 09 November 2020

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Study Overview

CLARITY will establish whether Angiotensin Receptor Blockers (ARBs) can reduce the severity of COVID-19. Pragmatic trial design embedded in routine care to avoid placing additional demands on busy health staff.
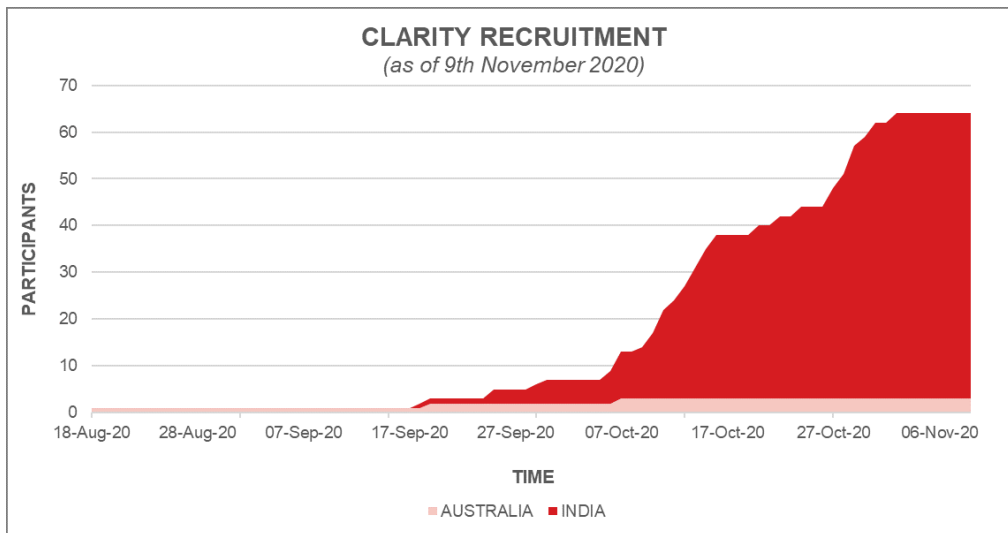
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Progress Updates

India

- 61 participants randomised (38 AIIMS Raipur, 23 Christian Hospital Nabarangpur,).
- 2 sites activated (Christian Hospital Nabarangpur, AIIMS Raipur)
- 8 sites undergoing set up (JIPMER Puducherry, LNJP Delhi, PSMC Gujarat, DR.RMLIMS Uttar Pradesh, PGIMER Chandigarh, GMCH Chandigarh, KMC Karnataka, CMC Punjab).

Australia

- 3 participants randomised (RPA Hospital).
- 11 sites activated (Canterbury, Concord, RPA, RNSH, Wollongong, St George, Austin, Prince of Wales, Sutherland, Sunshine and Westmead Hospitals).
- 5 sites initiated, undergoing set up (RPA Virtual, John Hunter, Liverpool, Alfred and Northern Hospitals).

CLARITY RECRUITMENT
(as of 9th November 2020)

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Total Participants Recruited: 64

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Upcoming Protocol Amendment

An amendment to the protocol was submitted to RPAH HREC on Thursday 29th October. The main change is to the inclusion criteria where time from diagnosis of SARS-CoV-2 infection to randomisation has been amended from 3, or 7, days to 10 days.

If you would like more information, please speak with your sponsor representative.

Project Timelines

MAR 2020	*Protocol Development*	*Done*
MAY 2020	*Study Set up Activities*	*Done*
JUN 2020	*First Site Activated*	*Done*
	MRFF Funding Received	
AUG 2020	*First Participant First Visit*	*Done*
NOV 2020	All Sites Activated – India & Australia	
	First Participant Last Visit	
DEC 2020	DSMB #1	
APR 2021*	Last Participant First Visit	
MAY 2021*	All Primary Outcome Data	
	Primary Analysis & Publication	
JUN 2021*	Last Participant Last Visit	
	Database Lock & All Sites Closed	
	Secondary Analyses & Publication	

* The trial utilises a Bayesian adaptive approach for sample size calculations and recruitment will continue until predefined superiority or futility rules are met. Minimum sample size = 700 (target: April 2021), maximum sample size = 2,200 (target: April 2022).