# Immuneglobulin (Human) Solution in Participants with Active COVID-19

## Study Design

A Prospective, Open-Label, Two-Arm, Parallel-Group, Randomized, Testing the efficacy and safety of a blood product COVID-19

## Study Details

### Study Title

Immuneglobulin (Human) plus standard of care versus only standard care in participants with active COVID-19

### Study Purpose

To evaluate the efficacy and safety of Immuneglobulin (Human) solution manufactured by Intas

### Principal Investigators

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### Sponsor

Lambda Therapeutic Research Ltd

### Study Endpoints

- All-cause mortality at day 28
- Composite clinical outcome assessed by following up to 14 days
- Mean change from Day 1 to Day 3 and Day 14 in clinical outcome

### Inclusion Criteria

- Participants with moderate or severe active COVID-19 (Clinical Management of COVID-19 Guidelines of MOHFW)
- Confirmed diagnosis of bacterial pneumonia or other active/uncontrolled fungal or viral infections at screening/baseline
- Currently receiving or has received in the last 14 days, experimental immune modulators, and/or monoclonal antibody therapies
- Documented medical history of known allergies, hypersensitivity, or IgG
- Gender: Adult male or female
- Childbearing status: Women of childbearing potential who are not currently pregnant or breastfeeding
- Evidence of use of a highly effective method of contraception described in Appendix 10.4

### Exclusion Criteria

- Participants who have received organ transplantation or major surgery in the past 6 months.
- Documented medical history of human immunodeficiency virus (HIV) antibody positive, or tests positive for HIV at Screening.
- Co-morbid systemic illnesses (uncontrolled diabetes, uncontrolled liver disease)
- Confirmed diagnosis of bacterial pneumonia or other active/uncontrolled fungal or viral infections at screening/baseline
- Currently receiving or has received in the last 14 days, experimental immune modulators, and/or monoclonal antibody therapies
- Documented medical history of known allergies, hypersensitivity, or IgG
- Gender: Adult male or female
- Childbearing status: Women of childbearing potential who are not currently pregnant or breastfeeding
- Evidence of use of a highly effective method of contraception described in Appendix 10.4

### Study Duration

- 2 days of screening period followed by 28 days of study period

### Protocol Number

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### Contact Information

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