

WORLD HEALTH ORGANIZATION TRIAL REGISTRATION DATA SET

DATA CATEGORY	INFORMATION
Primary registry and trial identifying number	ClinicalTrials.gov NCT03851783
Date of registration in primary registry	February 22, 2019
Secondary identifying numbers	Grand Challenges Canada: 1909-27795 Women and Children's Health Research Institute: WCHSSLDRP 2371
Source(s) of monetary or material support	Grand Challenges Canada Women and Children's Health Research Institute
Primary sponsor	Dr. Michael Hawkes (Investigator Initiated Study)
Secondary sponsor(s)	<ul style="list-style-type: none"> - University of Alberta - Makerere University - Ministry of Health Uganda
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Contact for scientific queries	Dr. Michael Hawkes; Telephone (+17802485540); Email (mthawkes@ualberta.ca), 3-588 Edmonton Clinic Health Academy, Faculty of Medicine, University of Alberta, Edmonton, Alberta, Canada
Public title	Effect of Solar Powered Oxygen Delivery on Childhood Mortality in Uganda
Scientific title	Effect of Solar Powered Oxygen Delivery on Childhood Mortality in Uganda: a cluster randomized trial
Countries of recruitment	Uganda
Health condition(s) or problem(s) studied	Pneumonia, hypoxemia
Intervention(s)	<i>Intervention:</i> Solar Powered Oxygen - Our system provides medical-grade oxygen to pediatric patients with hypoxemia, utilizing solar energy to power an oxygen concentrator to deliver therapeutic oxygen. An array of photovoltaic cells regulated by a charge controller, generates electricity, and charges a battery bank. A DC→AC inverter then provides power to the oxygen concentrator, which utilizes

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	<p>pressure swing absorption technology to concentrate medical-grade oxygen from ambient air.</p> <p><u>Control:</u> Selected sites yet to implement the solar powered oxygen delivery system.</p>
Key inclusion and exclusion criteria	<p><u>Inclusion Criteria (Hospital – Site Selection):</u></p> <ul style="list-style-type: none"> – Pediatric inpatient services – Lack of consistent oxygen supply on pediatric ward – Adequate space and willingness to install solar panels, battery bank, and concentrator on the hospital premises (pediatric ward). <p><u>Exclusion Criteria (Hospital – Site Selection):</u></p> <ul style="list-style-type: none"> – No inpatient services for children – Pre-existing, functional, consistent oxygen delivery system (cylinders or concentrator) – No space or unwilling to install solar panels, battery bank, and concentrator <p><u>Inclusion Criteria (Patients):</u></p> <ul style="list-style-type: none"> – Age < 5 years – Hypoxemia (SpO₂ < 92%) based on non-invasive pulse oximetry – Hospital admission warranted based on clinical judgement <p><u>Exclusion Criteria (Patients):</u></p> <ul style="list-style-type: none"> – SpO₂ ≥ 92% – Outpatient management – Denial of consent to participate in study – Known cyanotic cardiac condition – Neonatal diagnosis of hypoxic ischemic encephalopathy
Study type	<p><u>Type:</u> Interventional <u>Allocation:</u> Cluster Randomized <u>Intervention Model:</u> Stepped Wedge <u>Masking:</u> None <u>Primary purpose:</u> Prevention</p>
Date of first enrolment	June 1, 2019
Target sample size	<p><u>Health Facility Sites:</u> 20 <u>Patient Participants:</u> 2,400</p>
Recruitment status	Pending
Primary outcome(s)	Mortality at 48 hours after admission
Key secondary outcomes	In-hospital mortality, time of death

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	<p>Length of hospital stay</p> <p>Duration of supplemental oxygen therapy (time to wean O₂)</p> <p>Oxygen delivery system failure</p> <p>Costs (installation, servicing, maintenance)</p> <p>Nursing skills, baseline and skills retention</p>
Ethics Review	<p>Institutional Review Board of the University of Alberta: Approve – February 25, 2019; Telephone (+17804920459); Email (reoffice@ualberta.ca)</p> <p>Biomedical Sciences Research and Ethics Committee of Makerere University: Approved – March 5, 2019; Telephone (+256 75 25 75 050); Email (irbbiomedicalsciences@gmail.com)</p>
Completion date	May 31, 2021
Summary Results	Not yet enrolled
IPD Sharing Statement	<p>De-identified individual clinical trial participant level data (IPD) will be shared upon reasonable request submitted to the corresponding author.</p> <p>Findings will be disseminated through presentations at international conferences, and will be published in open access peer-reviewed journals for broad readership and to ensure that the data are available to health workers in low-middle income countries.</p> <p>At the conclusion of the study, we will hold a “town hall” meeting at participating health facilities, where local and global study data will be shared with the community members, with opportunities to ask questions.</p>