Clinical Trial Details (PDF Generation Date :- Mon, 01 Oct 2018 20:02:01 GMT)

CTRI Number	CTRI/2018/09/015833 [Registered on: 26/09/2018] - **Trial Registered Prospectively**
Last Modified On	24/09/2018
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Cohort Study
Study Design	Other
Public Title of Study	International, multi-centre study on comparing management and outcomes of children born with congenital diseases between Low-, Middle- and High?Income Countries.
Scientific Title of Study	Management and Outcomes of Congenital Anomalies in Low-, Middle- and High?Income Countries: A Multi-centre, International, Prospective Cohort Study

Secondary IDs if Any

Secondary ID	Identifier
NCT03666767	ClinicalTrials.gov

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> King’s Centre for Global Health and Health Partnerships, King’s College London, UK
> Wellcome Trust

Primary Sponsor

Primary Sponsor Details	
Name	Naomi Wright
Address	Paediatric Surgery Registrar and Clinical PhD Fellow, Kings Centre for Global Health and Health Partnerships, London, UK
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
Ankit Raj Dr Vijay Kumar Dr Sundeep PT	Kasturba Medical College and Kasturba Hospital, Manipal Academy of Higher Education, Manipal, Uudpi district, Karnataka- 576104, India

Countries of Recruitment

List of Countries
Afghanistan
Algeria
Angola
Argentina
Australia
Bangladesh
Belgium
Bolivia
Bosnia and Herzegovina
Brazil
Brunei Darussalam
Burundi
Cambodia
Cameroon
Canada
Chile
China
Colombia
Democratic Republic of the Congo
Ecuador
Egypt
Ethiopia
France
Germany
Ghana
Guatemala
India
Indonesia
Iraq
Jordan
Kenya
Lao People's Democratic Republic

Libyan Arab Jamahiriya
Lithuania
Madagascar
Malawi
Malaysia
Mauritania
Mexico
Morocco
Myanmar
Nepal
New Zealand
Nigeria
Other
Pakistan
Peru
Philippines
Poland
Republic of Korea
Rwanda
Saudi Arabia
Singapore
South Africa
Spain
Sudan
Sweden
Switzerland
Tanzania
Thailand
Tunisia
Turkey
Uganda
United Kingdom
United States of America
Uzbekistan
Venezuela (Bolivarian Republic of)
Zambia
Zimbabwe

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Ankit Raj	Kasturba Medical College and Kasturba Hospital	Department of Pediatric Surgery, Kasturba Medical College and Kasturba Hospital, Manipal Academy of Higher Education, Madhav Nagar, Manipal Udupi KARNATAKA	7259605314 arankitraj@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics

			Committee?
Institutional Ethics Committee	Approved	15/08/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Atresia of esophagus with tracheo-esophageal fistula
Patients	Atresia of esophagus without fistula
Patients	Congenital absence, atresia and stenosis of anus with fistula
Patients	Congenital absence, atresia and stenosis of anus without fistula
Patients	Congenital absence, atresia and stenosis of duodenum
Patients	Congenital absence, atresia and stenosis of ileum
Patients	Congenital absence, atresia and stenosis of jejunum
Patients	Congenital absence, atresia and stenosis of other parts of large intestine
Patients	Congenital absence, atresia and stenosis of rectum with fistula
Patients	Congenital absence, atresia and stenosis of rectum without fistula
Patients	Congenital diaphragmatic hernia
Patients	Congenital malformation of intestine, unspecified
Patients	Exomphalos
Patients	Gastroschisis

Intervention / Comparator Agent

Type	Name	Details
Intervention	Not Applicable	Not Applicable
Comparator Agent	Not Applicable	Not Applicable

Inclusion Criteria

Inclusion Criteria	
Age From	0.00 Day(s)
Age To	16.00 Year(s)
Gender	Both
Details	Any neonate, infant or child under the age of 16?years, presenting for the first time, with one of the study conditions listed below can be included in the study. 1. Oesophageal atresia with or without tracheo?oesophageal atresia 2. Congenital diaphragmatic hernia 3. Intestinal atresia 4. Gastroschisis 5. Exomphalos (also known as omphalocele) 6. Anorectal Malformation 7. Hirschsprung’s Disease

Exclusion Criteria

Exclusion Criteria	
Details	1. Any child above the age of 16-years. 2. Any neonate, infant or child with one of the study conditions who has previously received surgery for their condition. 3. If they have recently received surgery for their condition, were discharged and then represented with a complication of the surgery

	during the study period
Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
All-cause, in-hospital mortality.	30 days following primary intervention or primary admission

Secondary Outcome

Outcome	Timepoints
Complications occurring within 30-days of primary intervention including: 1. Surgical site-infection 2. Wound dehiscence 3. Need for re-intervention 4. Condition specific complications 5. Condition specific outcome variables 6. Length of hospital stay (time from admission to death in patients who do not survive) 7. 30-day post primary intervention mortality	30 days

Target Sample Size	**Total Sample Size=**27201 **Sample Size from India=**29
Phase of Trial	N/A
Date of First Enrollment (India)	01/10/2018
Date of First Enrollment (Global)	01/10/2018
Estimated Duration of Trial	**Years=**0 **Months=**4 **Days=**0
Recruitment Status of Trial (Global)	Not Yet Recruiting
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	none yet
Brief Summary	**Management and Outcomes of Congenital Anomalies in Low-, Middle- and High-Income Countries: A Multi-centre, International, Prospective Cohort Study** Congenital anomalies have risen to become the 5th leading cause of death in children under 5-years of age globally, yet limited literature exists, particularly from low- and middle-income countries (LMICs) where most of these deaths occur. This study aims to be the first large-scale, geographically comprehensive, multi-centre prospective cohort study of a selection of common congenital anomalies to define current management and outcomes globally. Results will be used to aid advocacy and global health prioritisation and inform future interventional studies aimed at improving outcomes. The Global PaedSurg Research Collaboration will be established consisting of children's surgical care providers from around the world to participate in the study; collaborators will be co-authors of resulting presentations and publication(s). Data will be collected on patients presenting primarily with seven congenital anomalies (oesophageal atresia, congenital diaphragmatic hernia, intestinal atresia, gastroschisis, exomphalos, anorectal malformation and Hirschsprung's disease) for a minimum of one month between Oct 2018 – April 2019. Anonymous data will be collected on patient demographics, clinical status, interventions and outcome. Data will be captured using the secure, online data collection tool REDCap. The primary outcome will be all-cause in-hospital mortality and the secondary outcomes will be occurrence of post-operative complications. Chi-squared analysis will be used to compare mortality between LMICs and HICs. Multilevel, multivariate logistic regression analysis will be undertaken to identify patient level and hospital level factors affecting outcomes with adjustment for confounding factors. P<0.05 will be deemed significant. Study approval will be sought from all participating centres. Funding has been granted by the Wellcome Trust for REDCap data analysis. There is no monetary support for local collaborators or for local ethical committee approval.