



Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 09:52:08 GMT)

<b>CTRI Number</b>	CTRI/2020/10/028289 [Registered on: 08/10/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	07/10/2020	
<b>Post Graduate Thesis</b>	Yes	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Diagnostic	
<b>Study Design</b>	Other	
<b>Public Title of Study</b>	Minimally Invasive Tissue Sampling and Postmortem Examination to Know the Cause of Death in Babies with 30 days of Age	
<b>Scientific Title of Study</b>	Minimally Invasive Tissue Sampling and Conventional Autopsy in Establishing Cause of Death in the Neonatal Period	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Kasturba Medical College and Hospital, Manipal Academy of Higher Education			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	NA			
<b>Address</b>	NA			
<b>Type of Sponsor</b>	Other [NA]			
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
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<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Kasturba Medical College and Kasturba Hospital Institutional Ethics Committee	Approved	31/08/2020	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Healthy Human Volunteers		Any married adult from the site (Karkala or Peravoor panchayat) who is interested to take	



	part in the study
Patients	Infection specific to the perinatal period, unspecified
Patients	Neonatal hemorrhage, unspecified
Patients	Other problems with newborn
Patients	Other specified conditions originating in the perinatal period
Patients	Respiratory distress syndrome of newborn
Patients	Unspecified chronic respiratory disease originating in the perinatal period

**Intervention /  
Comparator Agent**

Type	Name	Details
Intervention	Minimally Invasive Tissue Sampling (MITS)	Using MITS samples will be collected and examined. BARDMonopty needle will be used to collect samples using MITS technique. Samples will be processed and used for diagnosing cause of death
Comparator Agent	Conventional Autopsy	Conventional autopsy will be performed which is the gold standard Both techniques will be employed on same subject in which the new technique will be compared with gold standard test. Establishment in diagnosing cause of death using both techniques will be studied.

**Inclusion Criteria**

Inclusion Criteria	
Age From	0.00 Day(s)
Age To	30.00 Day(s)
Gender	Both
Details	Phase I: Approximately 10 in-depth interviews each from the community in Mala Panchayat, Karkala Taluk, Udupi District, Karnataka, and Peravoor Panchayat, Iritty Taluk, Kannur District, Kerala (till saturation is obtained).  10 married adult participants from both genders from 2 states who have children or experienced miscarriages or abortion    Phase II: 150 cases of neonatal deaths subjected to either conventional autopsy or MITS.  150 neonatal deaths occurring in NICU, Pediatrics, KMC, Manipal inclusive of bodies consented for an autopsy which has been retained in the Department of Pathology will be included in the study. In prospective cases, written parental consent will be obtained for MITS or conventional autopsy. In the case of retained bodies, consent has already been obtained for autopsy. 

**Exclusion Criteria**

Exclusion Criteria	
Details	Phase I: Unmarried adults of any gender  Phase II: Macerated babies and fetuses.

**Method of Generating  
Random Sequence**

Not Applicable

**Method of  
Concealment**

Not Applicable

**Blinding/Masking**

Not Applicable

**Primary Outcome**

Outcome	Timepoints
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	Phase I: Perceptions regarding neonatal autopsy, causes of death of a neonate, willingness of the community to know the cause of death and acceptance of MITS.  Phase II: Establishing the cause of death and coding of perinatal and neonatal deaths using the WHO ICD10 and ICD-PM.	Phase I- 72 weeks January 2021-June 2022  Phase II- 131 weeks October 2020-June 2023
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Phase II- Coding of perinatal and neonatal deaths using the WHO ICD10 and ICD-PM.	131 weeks October 2020-June 2023
<b>Target Sample Size</b>	<b>Total Sample Size=150</b> <b>Sample Size from India=150</b> <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b> <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	15/10/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=3</b> <b>Months=0</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Not Yet Recruiting	
<b>Publication Details</b>	Nil	
<b>Brief Summary</b>	<p><b>INTRODUCTION</b></p> <p>Perinatal deaths account for 7% of the global burden of disease. Accurate diagnosis of the cause of fetal, perinatal, and neonatal death is important for the prevention of deaths and morbidity in subsequent pregnancies. In fifty percent of the cases, the certified cause of death can be discordant from the actual cause of death and hence the need for a post-mortem examination. A conventional autopsy is a gold standard in confirming and establishing the cause of death in the perinatal and neonatal period especially when clinical manifestations are nonspecific. It includes a thorough examination of the whole body with dissection of organs and body cavities, followed by sectioning of relevant tissues to establish the cause of death and the effectiveness and side effects of therapies. India being a conservative multicultural nation, many parents refuse to consent for autopsy in neonates due to religious, emotional attachment, and cultural reasons. Public reluctance for autopsy has increased over time, more so due to adverse media attention, delay in last rites, and spiritual or ethnic views, and fear of disfigurement of the deceased's body, has led to refusal for conventional autopsy and preferential acceptance for Minimally Invasive Tissue Sampling (MITS). It is a feasible and less traumatic technique that would circumvent the need for a complete autopsy in determining the cause of death. This technique is less invasive and time-consuming and practical in socially constrained areas.</p> <p><b>RESEARCH QUESTION</b></p> <p>Can minimally invasive tissue sampling be an alternative to a conventional autopsy?</p>	



### STUDY DESIGN

This is a three-year prospective and retrospective study conducted in the Departments of Pathology and Pediatrics (Neonatology) in Kasturba Medical College & Hospital, Manipal, Karnataka

The study is divided into two phases

- Phase I – Qualitative study on community perceptions on conventional autopsy and MITS
- Phase II – Prospective and retrospective study on minimally invasive tissue sampling and conventional autopsy to establish the cause of death (CoD)

### OUTCOME EXPECTED

- Phase I of the study - Thematic analysis of the interviews will reveal the perceptions regarding neonatal autopsy, causes of death of a neonate, willingness of the community to know the cause of death, and acceptance of MITS.
- Phase II- Establishing the cause of death and coding of perinatal and neonatal deaths using the WHO ICD10 and ICD-PM.

### IMPORTANCE OF THE RESEARCH

- Establishing the cause of death
- Prevention of deaths and morbidity in subsequent pregnancies
- The perceptions of the community towards autopsy practices are also important to improve neonatal mortality and recommend changes in health policies.
- Help in identifying the perceptions and acceptance of the community towards autopsy practices and the acceptance of MITS versus conventional autopsy in cases of neonatal deaths.