



Clinical Trial Details (PDF Generation Date :- Fri, 24 Sep 2021 04:28:25 GMT)

<b>CTRI Number</b>	CTRI/2019/09/021178 [Registered on: 11/09/2019] - <b>Trial Registered Retrospectively</b>	
<b>Last Modified On</b>	09/09/2019	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Diagnostic Preventive	
<b>Study Design</b>	Cluster Randomized Trial	
<b>Public Title of Study</b>	A ?study to see the effect of screening ?for mouth and food pipe cancer using visual ? examination and x ray	
<b>Scientific Title of Study</b>	Effect of screening with visual examination and double contrast barium swallow on oral and upper aerodigestive tract cancer mortality- a cluster randomized trial.	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	705, Project Number	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	Dr CS Pramesh
	<b>Designation</b>	Professor and Surgical Oncologist
	<b>Affiliation</b>	Tata Memorial Hospital
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<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Tata Memorial Centre, Room No 301, 3rd Floor, Homi Bhabha Block, Dr. E Borges Marg, Parel east, Mumbai-400012			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	Department of Atomic Energy			
<b>Address</b>	R&D II-Section Anushakti Bhavan C.S.M Marg Mumbai 400001			
<b>Type of Sponsor</b>	Government funding agency			
<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>
	Dr CS Pramesh	Tata Memorial Hospital	Room No 301, 3rd Floor, Homi Bhabha Block, Dr. E Borges Marg, Parel Mumbai MAHARASHTRA	022-24177070 prameshcs@tmc.gov.in
<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>
	Human Ethics Committee-I	Approved	30/04/2010	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		High risk of eosophageal and hypopharyngeal cancers-chronic tobacco users(cumulative use more than 5 years) (or) betel nut and areca nut chewers (or) alcohol users(cumulative more than 5 years)	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Screening with health education	Subjects will be screened routinely for cancer in addition of health education and counselling on cessation of tobacco and alcohol use. Further treatment of screen positives.	
	Comparator Agent	Control	Subjects will only be provided health education and counselling on cessation of tobacco and alcohol use.	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	35.00 Year(s)		
	<b>Age To</b>	65.00 Year(s)		
	<b>Gender</b>	Both		



	<b>Details</b>	Individuals at high risk of esophageal and hypopharyngeal cancers-chronic tobacco users(cumulative use more than 5 years) (or) betel nut and areca nut chewers (or) alcohol use (cumulative use more than 5 years)
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	1. People with low performance status ( ECOG score > 2) 2. Patients with pre existing symptoms of esophageal and hypopharyngeal cancers (persistent dysphagia, odynophagia and/or hoarseness)
<b>Method of Generating Random Sequence</b>	Other	
<b>Method of Concealment</b>	Not Applicable	
<b>Blinding/Masking</b>	Open Label	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Reduction in esophageal and hypopharyngeal cancer related- mortality and oral cancer related mortality.	Five years after completion of screening
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	1. Improvement in survival after diagnosis of esophageal and hypopharyngeal cancers. 2. Diagnostic sensitivity and specificity of double contrast barium swallow in diagnosis of asymptomatic esophageal and hypopharyngeal cancers. 3. Cost effectiveness of screening for esophageal and hypopharyngeal cancers in community. 4. Assess possible aetiological factors associated with causation of esophageal and hypopharyngeal cancers.	Five years after completion of screening
<b>Target Sample Size</b>	<b>Total Sample Size=110000</b> <b>Sample Size from India=110000</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>	Phase 3	
<b>Date of First Enrollment (India)</b>	01/05/2010	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=10</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>	Open to Recruitment	
<b>Publication Details</b>	none	
<b>Brief Summary</b>	<p>Esophageal and hypopharyngeal cancers are a common problem worldwide and are important <small>public health</small> problems in India. They are highly aggressive neoplasms and are associated with a poor prognosis. These cancers of the upper aerodigestive tract are common in the developing world in men with high risk factors like tobacco, betel and arecanut and alcohol use. Esophageal cancer is the eighth most common cancer worldwide and more than 400,000 cases diagnosed every year. Squamous esophageal cancer continues to be the major problem in the developing world while there has been a major shift in the epidemiological profile in the developed world with a virtual epidemic of esophageal adenocarcinoma. Hypopharyngeal cancers are far more common in the developing world than the west and are closely associated with tobacco and alcohol use. Both esophageal and hypopharyngeal cancers are a major public health problem in most parts of India with some specific areas in India having a high incidence of these cancers. This study will help to understand the effect of visual screening and use of barium contrast x-ray screening for above mentioned cancers. On randomization it will be studied that what could be the impact of early screening with proper education and counselling on death rate or mortality rate.</p>	