



Clinical Trial Details (PDF Generation Date :- Sun, 08 Jan 2023 05:55:16 GMT)

CTRI Number	CTRI/2021/06/034308 [Registered on: 18/06/2021] - Trial Registered Prospectively	
Last Modified On	03/06/2022	
Post Graduate Thesis	No	
Type of Trial	Observational	
Type of Study	Epidemiological	
Study Design	Other	
Public Title of Study	Nurse Based Genetic Counseling for Hereditary Womens Cancer	
Scientific Title of Study	Nurse led Genetic Counselling in Improving Awareness and Implementation of screening services for hereditary womens cancer NuGenA	
Secondary IDs if Any	Secondary ID	Identifier
	Nil	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Ovarcome Chittaranjan National Cancer Institute			
Primary Sponsor	Primary Sponsor Details			
Name	Chittaranjan National Cancer Institute			
Address	37, S.P Mukherjee Road Bakul Bagan Kolkata 700026			
Type of Sponsor	Research institution and hospital			
Details of Secondary Sponsor	Name	Address		
	KolGOTrg	Room 404, CNCI, 37, S.P Mukherjee Road Bakul Bagan, Kolkata 700026		
Countries of Recruitment	List of Countries			
	India			
	Nepal			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Asima Mukhopadhyay	Chittaranjan National Cancer Institute	Department of Gynecological Oncology Room no 404A 37, Shyama Prasad Mukherjee Road Kolkata WEST BENGAL	7044088132 asima7@yahoo.co.in
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institution Ethics Committee, Chittaranjan National Cancer Institute	Approved	04/12/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Malignant neoplasm of ovary	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Nil	Nil	
	Comparator Agent	Nil	Nil	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	60.00 Year(s)		
	Gender	Female		
	Details	a) All non-mucinous epithelial ovarian cancer irrespective of their age b) All first degree and second degree relatives of women diagnosed with epithelial ovarian cancer and found to have deleterious mutation in BRCA1 or 2 c) If further funding is		



	<p>available: Then testing according to the NCCN guidelines
 for Hereditary Breast and Ovarian cancer risk assessment
 1. Personal history of breast cancer and ?1 of these:
 ? Diagnosed at age ?45 years
 ? Diagnosed at age ?50 years with ?1 close blood relatives with breast cancer at
 age 50 years and/or ?1 close blood relatives with epithelial ovarian cancer at
 any age
 ? 2 breast primaries when first breast cancer diagnosis occurred at age ?50 years
 ? Diagnosed at age ?60 years with a triple negative breast cancer
 ? Diagnosed at age ?50 years with a limited family history
 ? Diagnosed at any age with ?2 close blood relatives with pancreatic cancer at
 any age
 Close male blood relative with breast cancer
 Individual of ethnicity associated with higher mutation frequency (e.g.,
 Ashkenazi Jewish)
 Personal history of epithelial ovarian cancer
 ? Personal history of male breast cancer
 Personal history of pancreatic cancer at any age with ?2 close blood relatives
 with breast and/or ovarian cancer and/or pancreatic cancer at any age
 2. No personal history of breast cancer, but ?1 of these:
 ? First- or second-degree blood relative meeting any of the above criteria
 Third-degree blood relative with breast cancer and/or ovarian cancer with ?2
 close blood relatives with breast cancer (?1 with breast cancer at age ?50
 years) and/or ovarian cancer</p>	
Exclusion Criteria	Exclusion Criteria	
	Details	Any patient who does not meet the inclusion criteria
Method of Generating Random Sequence	Other	
Method of Concealment	Other	
Blinding/Masking	Not Applicable	
Primary Outcome	Outcome	Timepoints
	To identify whether implementation of nurse led genetic clinic supported by patient public involvement is cost-effective Identifying more individuals at risk of cancers through awareness and screening campaigns. Improving the uptake of genetic testing and referrals. In the longer term, reduction in women being diagnosed with advanced breast-ovarian cancers in a defined geographical area 5. Economic analysis of such approach where the cost of facility is part-borne by local community	3 years
Secondary Outcome	Outcome	Timepoints
	Assess acceptability and embeddedness (population/ provider/governmental level)	2 years
	Compare local community satisfaction (rates and qualitative) between screening camps facilitated and organized by PPI and local champions versus those organized by conventional institutional initiated efforts	2 years
	Study willingness to pay (WTP) for screening	2 years



	and genetic testing in population attending the screening camps	
	Assessing differences in service implementation (barriers and solutions and risk/harm) for this model in rural versus urban and different socio-economic strata which would inform upscaling it within India and eventually to other LMICs	2 years
	Evaluate the training programme of developing nurse genetic counsellors as measured by success of implementing a West Bengal Health University affiliated course of genetic counselling and interest/uptake of nursing and allied health care professionals in attending such courses	2 years
Target Sample Size	Total Sample Size=200 Sample Size from India=100 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials	
Phase of Trial	N/A	
Date of First Enrollment (India)	01/07/2021	
Date of First Enrollment (Global)	01/07/2021	
Estimated Duration of Trial	Years=3 Months=0 Days=0	
Recruitment Status of Trial (Global)	Not Yet Recruiting	
Recruitment Status of Trial (India)	Open to Recruitment	
Publication Details	N/A	
Brief Summary	<p>We are proposing a strategy where a nurse led genetic counselling service (intervention) whereby nurses/medical social workers after adequate training, will develop a community-based program for health education, cancer awareness and genetic counselling/referral services in Eastern India. This model has not been evaluated in Eastern India before and can be an exemplar of a cost effective approach of involving both the provider and acceptor of existing cancer health services to improve primary and secondary prevention in women's cancer. The key aim of this proposal is to evaluate whether such strategy will be acceptable, cost-effective, and scalable for all stakeholders i.e., patients, health care professionals, government/policy makers across diverse health infrastructural landscapes in low middle-income countries.</p>	