



Clinical Trial Details (PDF Generation Date :- Fri, 27 Jan 2023 18:48:06 GMT)

CTRI Number	CTRI/2012/03/002483 [Registered on: 07/03/2012] - Trial Registered Prospectively	
Last Modified On	21/07/2014	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Drug	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial	
Public Title of Study	To Evaluate the effect of Metformin versus Placebo as an Add-on Therapy in patients with recurrent epithelial ovarian cancer receiving chemotherapy: A double blind randomized controlled clinical trial.	
Scientific Title of Study	To Evaluate the effect of Metformin versus Placebo as an Add-on Therapy in patients with recurrent epithelial ovarian cancer receiving chemotherapy: A double blind randomized controlled clinical trial.	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr Saphalta Baghmar
	Designation	Senior Resident
	Affiliation	
	Address	Department of Medical Oncology Dr. Bhim Rao Ambedkar Institute and Rotary Cancer Hospital, AIIMS, New Delhi South DELHI 110029 India
	Phone	9811446828
	Fax	
	Email	drbsaphalta@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Saphalta Baghmar
	Designation	Senior Resident
	Affiliation	
	Address	Department of Medical Oncology Dr. Bhim Rao Ambedkar Institute Rotary Cancer Hospital, AIIMS, New Delhi South DELHI 110029 India
	Phone	9811446828
	Fax	
	Email	drbsaphalta@gmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Saphalta Baghmar
	Designation	Senior Resident
	Affiliation	
	Address	Department of Medical Oncology Dr. Bhim Rao Ambedkar Institute Rotary Cancer Hospital, New Delhi South DELHI 110029 India



	Phone	9968125074		
	Fax			
	Email	drbsaphalta@gmail.com		
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Dr Reddys Laboratories Ltd.			
Primary Sponsor	Primary Sponsor Details			
	Name	Dr Reddys Laboratories Ltd		
	Address	6-3-1192/1/1, Block I 5th Floor, White House Kundanbagh, Begumpet Hyderabad, A.P. 500016 Tel- 040-66022500 08		
	Type of Sponsor	Pharmaceutical industry-Indian		
Details of Secondary Sponsor	Name	Address		
	NIL	NIL		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Dr Lalit Kumar	AIIMS	Department of Medical Oncology Dr. BRA IRCH, AIIMS, New Delhi South DELHI	9811446828 lalitaiims@yahoo.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	AIIMS Ethics committee, AIIMS New Delhi	Approved	02/01/2012	No
Regulatory Clearance Status from DCGI	Status		Date	
	Approved/Obtained		13/10/2011	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Recurrent Epithelial Ovarian Cancer	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	metformin	Dose - 500 mg twice daily orally for one year	
	Comparator Agent	placebo(starch powder)	Dose - 500 mg twice daily orally for one year	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	70.00 Year(s)		
	Gender	Female		
	Details	Patients of recurrent epithelial ovarian cancer Age more than 18 years and up to 70 years 		
Exclusion Criteria	Exclusion Criteria			
	Details	Patient with diabetes mellitus Patients who have received metformin or another mTOR inhibitor in the last 2 years Patients with deranged liver or renal profile Patients with known hypersensitivity to metformin		



Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	Centralized	
Blinding/Masking	Participant and Investigator Blinded	
Primary Outcome	Outcome	Timepoints
	prolonging progression free survival	patients will be followed for 1 year and time to relapse will be noted
Secondary Outcome	Outcome	Timepoints
	i) To evaluate response rate in two arms ii) To study the toxicity profile in two groups iii) To evaluate overall survival in two groups iv) To compare the Quality of life between two groups	1 year
Target Sample Size	Total Sample Size=100 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	Phase 3	
Date of First Enrollment (India)	07/03/2012	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=1 Months=0 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Closed to Recruitment of Participants	
Publication Details		
Brief Summary	Patients with recurrent epithelial ovarian cancer undergoing chemotherapy will be randomized either to metformin or placebo arm	