

DIVISION OF CLINICAL TRIALS

St. John's Research Institute, Bangalore

Dr. Prem Pais, Dr. Denis Xavier, Dr. Alben Sigamani, Freeda Xavier, Nandini Mathur

Academic Collaborators

Completed Studies

Trial	Title	Publication	Sponsor	Sample size	
				Global	India
CVD epidemiology [28,500]					
ICMR	National C-C in AMI- A case control study to study the risk factors for AMI in Indians		ICMR	-----	2000
INTERHEART	A study which evaluated the association of risk factors for AMI in native South Asians, especially at younger ages, when compared with individuals from the other countries	Lancet-Sep 2004	PHRI	29972	14000 cases and 16000 controls
CREATE ACS Registry	A registry that examined the treatment patterns and outcome of ACS patients with renal dysfunction	Lancet-2008	DCT, PHRI, Sanofi aventis		20468
Large Clinical Trials (160+ institutions, 60+ cities)					
CREATE	To evaluate Reviparin and GIK in AMI	JAMA-2004 AHJ-2004	PHRI	20,201	8060
POISE	To evaluate β blockers (metoprolol) in PeriOperative Ischemia	Lancet-08	CIHR	8351	777
PROFESS	Dipyridamole plus ASA Vs Clopidogrel & Telmisartan Vs placebo in ischemic stroke	NEJM-2008	BI	20,333	1,620
OASIS 5	Fondaparinux Vs Enoxaparin in acute treatment of unstable/ non- ST-segment elevation MI	NEJM-2006	PHRI/GSK Sanofi Aventis	20,078	522
TIMACS	Timing of Intervention (early versus delayed) in ACS	AHA 2008	PHRI	3031	31
OASIS 6	Fondaparinux Vs placebo in patients with STEMI	JAMA-2007	PHRI/GSK/ Sanofi aventis	12,092	1444
CURRENT	A comparative study between standard and high dose of clopidogrel in patients with unstable angina or non-ST segment elevation MI managed with an early invasive strategy	-----	Sanofi aventis	25000	2250
OASIS-8/ FUTURA	A trial to evaluate standard Vs low dose adjunctive i.v. UFH in patients undergoing PCI	-----	GSK	2000	500
MARS	A five armed prospective study to determine the safety, efficacy & tolerability of SelomaxTM with Metoprolol XL & amlodipine as individual components in Indians	-----	AstraZeneca	-----	400
POLYCAP	To determine the efficacy and safety of a POLYCAP Vs its components in subjects with at least one CV risk factors	Lancet March 2009	Cadila	-----	2053
RELY	Dabigatrin Vs warfarin in atrial fibrillation	NEJM, Lancet	PHRI/BI	18113	578
VITATOPS	To evaluate the efficacy and safety of multi-vitamin therapy in secondary stroke prevention	Int Journal of Stroke, Vol 2 May 2007	Royal Perth Hospital	8167	1421

On going Studies

Trial	Title	Sponsor	Sample size	
			Global	India
AVVEROES	A double blind, randomized trial of apixaban Vs acetyl salicylic acid to prevent stroke in atrial fibrillation patients who had failed or are unsuitable for Vit- K antagonist	PHRI/BI	5000	203
ARISTOTLE	A randomized double blind, parallel arm study to evaluate the treatment efficacy and safety of apixaban in preventing stroke and systemic embolism in subjects with nonvascular atrial fibrillation	BMS	18,000	601
ASPIRE	A randomized, double-blind, placebo- controlled trial conducted for determining the efficacy and safety of low- dose aspirin after initial anticoagulation to prevent the recurrent of venous thromboembolism	NHMRC, Australia	2000	400
INTERSTROKE	A case-control study for determining the importance of conventional and emerging risk factors for stroke	PHRI, CIHR, BI	20,000	4000
HOPE-3	A trial to evaluate the safety and efficacy of rosuvastatin and cadesartan/ hydrochlorothiazide and their combinations in middle aged people, who are at intermediate risk for vascular events	PHRI, CIHR, AstraZeneca	11000	2000
RECREATE	A intensive insulin therapy targeting normoglycemia in acute MI	SanofiAventis	287	273
VISION	A large cohort study to evaluate major vascular events in patients undergoing non-cardiac surgery	DCT	8000	2000
RELY AF Registry	An observational study to determine predisposing condition & regional variations in the management of atrial fibrillation/ flutter	BI	15000	1500
RIVAL	A randomized double blind study in patients with unstable angina/ MI managed with early invasive strategy, comparing a high loading dose regimen of clopidigrel Vs standard dose	Sanofi aventis	7000	340
TIPS-K	A randomized trial to evaluate low strength polycap two doses of low strength polycap & of low strength K+ supplementation in patients with stable CVD/ ischemic heart disease	Cadila	-----	500
WELL/COME/ TIPS-3	A clinical trial of polypill in primary prevention setting to reduce cardiovascular disease (CVD) outcomes	Wellcome Trust/ Cadila	5000	2500
FRIENDS	A Prospective Study of Practice Patterns and Outcomes in Chronic Disease in an Urban Family Practice	DCT	-----	4000
AMEND	An ongoing program (research, projects, patient management strategies & knowledge translation approaches) to prevent & manage CVDs in India	AstraZeneca	-----	10,000
APPRAISE2	A trial to evaluate Apixaban in patients with recent ACS	BMS/ Pfizer	10,000	1078
Studies to be initiated in 2010 [-42,000]				
APOLLO	A randomized controlled trial of aliskiren in the prevention of major cardiovascular events in elderly people	Novartis	11,000	1600
MACE Registry	A nation wide observational study in Acute Coronary Syndrome (ACS)	ICMR	-----	10,000+
PEGASUS	A randomized study in MI patients for preventing the secondary thrombotic events with Ticagrelol	AstraZeneca	13,500	400
PALLAS	A study to evaluate dronedarone in permanent atrial fibrillation patients & to demonstrate that it reduces vascular events in these patients	Sanofi aventis	11,000	600
EDPS	A pilot study for the Early Diagnosis & Prevention System CVD Prevention Model	George Institute	-----	3000
NHLBI/ UH- Projects				
INSPIRE	An observational study to determine etiologies, clinical practice patterns and outcomes of strokes in India	NHLBI/ UH		10,500
SPREAD	A randomized trial comparing post discharge interventions to standard care in ACS patients	NHLBI/ UH		800
PREPARE	A cluster randomized trial to evaluate primary prevention strategies at the community level to promote treatment adherence to prevent cardiovascular disease	NHLBI/ UH		27,000

List of Abbreviations

AMI- Acute Myocardial Infraction	ACS- Acute Coronary Syndrome	BI- Boehringer Ingelheim
GSK- GlaxoSmithKline	BMS- Bristol Myers Squibb	DCT- Division of Clinical Trials
PCI- Percutaneous Coronary Intervention	CVD- Cardio Vascular Disease	CIHR_ Canadian Institute of Health Research
UFH- Unfractionated Heparin	U H- United Health	GIK_ Glucose Insulin Potassium
PHRI- Population Health Research Institute		ICMR- India Council of Medical Research
STEMI- ST Segment Elevation Myocardial Infraction		NHLBI- National Heart Lung & Blood Institute

Journals

Government collaborators