

UMPIRE TRIAL COLLABORATORS

**Imperial College
London**

Imperial College London and
Imperial College Healthcare NHS Trust

Imperial College Healthcare **NHS**
NHS Trust



Royal College of
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Universitair Medisch Centrum
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Dr. Reddy's Laboratories Ltd



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THE GEORGE INSTITUTE
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CENTRE FOR CHRONIC DISEASE CONTROL

Centre for Chronic Disease Control, Delhi

Project Title	A randomised controlled open-label trial of a fixed-dose combination (FDC) medication (the Red Heart Pill) and usual care in those at high risk of cardiovascular disease.		
Key Words	Red Heart Pill polypill Fixed dose combination Cardiovascular disease Adherence		
Trial Funder and Sponsor	European Commission (FP7 Grant) - Project Ref No : 241849	 	Trial Sponsor Imperial College London, U.K.
Trial Website	www.spacecollaboration.org The SPACE (Single Pill to Avert Cardiovascular Events) group includes collaborators involved in clinical trials of a polypill strategy for CVD prevention.		
Timelines	Start : 01 FEB 2010 End : 31 JAN 2013 Recruitment : 12 months Follow-up : 15 months (average)		
Enrolment	ACTUAL RANDOMISED (as of 26JUL11): 1004 Europe; 1000 India, TOTAL 2004		
Background	People with established cardiovascular disease (people who have had a stroke or heart attack) need secondary prevention that addresses multiple risk factors. Complexity & cost confer particularly difficult barriers to uptake of treatment; recovery from a stroke or heart attack typically requires prescription of multiple medications for cholesterol, blood pressure and platelet function. A low-cost, once daily, fixed-dose combination (FDC) polypill, the Red Heart Pill, has been formulated by Dr Reddy's Laboratories. This Red Heart Pill contains 4 medicines which have been available and safely used for years and are now combined in a single pill.		
Aims	UMPIRE will assess whether people prefer taking medication for the prevention of heart attacks and strokes as a single pill or as several separate tablets (adherence to medications) and if it improves clinical outcomes (the risk of having further cardiovascular events) among high-risk patients in Europe (UK, Ireland and Netherlands) and India. The results will be used to develop recommendations for equitable access.		
Red Heart Pill (RHP)	Red Heart Pill, version 1 aspirin 75mg , lisinopril 10mg simvastatin 40mg atenolol 50mg	Red Heart Pill, version 2 aspirin 75mg , lisinopril 10mg simvastatin 40mg hydrochlorothiazide 12.5mg	
Trial Results	Results show that access to FDCs in people with CVD or similarly high risk improves adherence, blood pressure and cholesterol levels. AHA Abstract - http://circ.ahajournals.org/content/126/23/2776		
Trial Registration	EudraCT: 2009-016278 Clinicaltrials.gov: NCT01057537 Clinical Trials Registry – India : CTRI/2010/091/000250		
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