

<b>Project Title</b>	UMPIRE: a randomised controlled open-label trial of a fixed-dose combination polypill medication (the Red Heart Pill) and usual care in those at high risk of cardiovascular disease.					
<b>Trial Funder</b>	European Commission (FP7 Grant) - Project Ref No : 241849					
<b>Trial Sponsor</b>	Imperial College London, U.K.					
<b>Trial Website</b>	www.spacecollaboration.org					
<b>Key Words</b>	<b>Polypill Red Heart Pill Cardiovascular disease Adherence Equitable access</b>					
<b>Timelines</b>	Start : 01 FEB 2010                      End : 31 JAN 2013 Recruitment : 12 months              Follow-up : 18 months (average)					
<b>Enrolment</b>	2000 participants (1000 Europe; 1000 India)					
<b>Background</b>	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, fixed-dose, once-daily combination polypill, the Red Heart Pill, has been formulated by Dr Reddy's Laboratories. This Red Heart Pill contains 4 ingredients - aspirin, 2 blood pressure-lowering medicines and a cholesterol-lowering medicine. These 4 medicines have been available and safely used for many years and now they have been combined in a single pill.					
<b>Aims</b>	UMPIRE will assess whether people prefer taking medication for the prevention of heart attacks and strokes as a single pill or in the usual style 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.					
<b>Red Heart Pill</b>	<table border="1"> <thead> <tr> <th>Red Heart Pill, version 1</th> <th>Red Heart Pill, version 2</th> </tr> </thead> <tbody> <tr> <td>aspirin 75mg simvastatin 40mg lisinopril 10mg <b>atenolol 50mg</b></td> <td>aspirin 75mg simvastatin 40mg lisinopril 10mg <b>hydrochlorothiazide 12.5mg</b></td> </tr> </tbody> </table>	Red Heart Pill, version 1	Red Heart Pill, version 2	aspirin 75mg simvastatin 40mg lisinopril 10mg <b>atenolol 50mg</b>	aspirin 75mg simvastatin 40mg lisinopril 10mg <b>hydrochlorothiazide 12.5mg</b>	
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<b>Trial Registration</b>	EudraCT: 2009-016278 Clinicaltrials.gov: NCT01057537 Clinical Trials Registry – India : CTRI/2010/091/000250					
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