Project Title: 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.

Trial Funder: European Commission (FP7 Grant) - Project Ref No: 241849

Trial Sponsor: Imperial College London, U.K.

Trial Website: www.spacecollaboration.org

Key Words: Polypill, Red Heart Pill, Cardiovascular disease, Adherence, Equitable access

Timelines:
- Start: 01 FEB 2010
- End: 31 JAN 2013
- Recruitment: 12 months
- Follow-up: 18 months (average)

Enrolment: 2000 participants (1000 Europe; 1000 India)

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, 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.

Aims: 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.

Red Heart Pill:

<table>
<thead>
<tr>
<th>Red Heart Pill, version 1</th>
<th>Red Heart Pill, version 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>aspirin 75mg</td>
<td>aspirin 75mg</td>
</tr>
<tr>
<td>simvastatin 40mg</td>
<td>simvastatin 40mg</td>
</tr>
<tr>
<td>lisinopril 10mg</td>
<td>lisinopril 10mg</td>
</tr>
<tr>
<td>atenolol 50mg</td>
<td>hydrochlorothiazide 12.5mg</td>
</tr>
</tbody>
</table>

Trial Registration:
- EudraCT: 2009-016278
- Clinicaltrials.gov: NCT01057537
- Clinical Trials Registry – India: CTRI/2010/091/000250

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