

International trial finds polypill halves predicted heart disease and stroke risk

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The world's first international polypill trial has shown that a four-in-one combination pill can halve the predicted risk of heart disease and stroke. The results are published online today in the open access journal *PLoS One*.

The once-a-day polypill contains aspirin and agents to [lower blood pressure](#) and cholesterol. These drugs are currently prescribed separately to millions of patients and are known individually to cut the risk of disease, but many experts believe that combining them into a single pill will encourage people to take the medications more reliably.

The trial tested the effectiveness and tolerability of the polypill in 378 people with raised risk of [cardiovascular disease](#), who did not necessarily have [high blood pressure](#) or cholesterol, against a placebo. The participants came from the UK, Australia, Brazil, India, New Zealand, The Netherlands, and the USA, with core funding for the central coordination of the trial provided by the Wellcome Trust.

"The results show a halving in [heart disease](#) and stroke can be expected for people taking this polypill long-term," said Professor Anthony Rodgers of The George Institute for [Global Health](#), who led the international consortium.

"We know from other trials that long-term there would also be a 25-50% lower death rate from [colon cancer](#), plus reductions in other major cancers, [heart failure](#) and [renal failure](#)," Professor Rodgers said. "These

benefits would take several years to 'kick in', but of course one of the hopes with a polypill is it helps people take medicines long-term."

National trials of similar combination 'polypill' treatments have previously been conducted in India, Iran and Sri Lanka, but this is the first trial to combine data from patients at international centres and the first to look reliably at the incidence of [side effects](#) against a placebo.

The authors noted that the benefits, while large, were not as massive as previous researchers have suggested, and the side effects were also not as rare as first thought. In the short-term about 1 in 6 people experienced a side effect. Most were mild but about 1 in 20 overall stopped treatment due to side effects, indicating that treatment is best targeted to those at raised risk of disease.

Professor Simon Thom of Imperial College London, who led the UK arm of the trial, commented: "We now need to conduct larger trials to test whether these medicines are best provided in the form of a polypill, or as separate medicines, and whether this combination strategy improves patient adherence to cardiovascular medication."

This polypill will be available in India soon and then elsewhere within a few years, according to regulatory timelines within each individual country.

Dr Ted Bianco, Director of Technology Transfer at the Wellcome Trust, commented: "Few of us would dissent from the view that prevention is better than cure in most matters medical. It is good news, indeed, to see the evidence base grow for the potential use of a new generation of combination products as a safe and affordable option in the battle against heart attack and stroke."

In the UK, around one in three of all deaths are attributable to

cardiovascular disease. Globally, around 80% of all deaths from cardiovascular disease and diabetes occur in low or middle income countries, according to recent estimates.

In 2001, the World Health Organisation and the Wellcome Trust convened a meeting of experts to discuss affordable interventions for non-communicable diseases, including the potential of a fixed-dose combination pill to reduce the risk of cardiovascular diseases. From here a programme of research was outlined to assess whether this approach is safe, effective and practical.

Provided by Wellcome Trust

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