

# Global trials of 'super pill' a step closer

Global clinical trials are to begin on an inexpensive pill that holds promise to halve the risk of heart disease and stroke. Development of the pill has been led by a team at The University of Auckland's Clinical Trials Research Unit.

The Health Research Council of New Zealand (HRC) supported early research into the 'polypill' which has been manufactured in India and is now jointly funding trials with the Wellcome Trust in the UK.

The tablet contains aspirin and agents to lower blood pressure and cholesterol. It was rejected by traditional pharmaceutical companies as it was so inexpensive that it offered little financial incentive. Instead, The University of Auckland has formed a public-private partnership with a leading manufacturer in India, bolstered by grants from agencies including the HRC.

Professor Anthony Rodgers, who is leading the 12-week PILL pilot trial in New Zealand, said: "After five years of hard work on this project, securing funding and overcoming considerable formulation challenges, we are delighted that recruitment for the trials has finally begun."

"If the treatment really does safely halve cardiovascular disease, is well accepted and cost a few cents a day, then it will be a breakthrough. But the key thing now is to put it to scrutiny in a clinical trial."

The trial will include 400 people from New Zealand, Australia, Brazil, India, the Netherlands, the UK and the USA. Recruitment has started in the UK and The Netherlands and volunteers are now needed in Auckland.

"Cardiovascular risk is measured through a combination of factors, including cholesterol and blood pressure levels, smoking, family history and being overweight. The trial will test whether we can identify patients with increased risk early, and safely reduce risk factors with a single, once a day tablet," said Professor Rodgers.

The 12-week trial of the pill, will assess its tolerability and effects on blood pressure and cholesterol. The study is looking for volunteers who are not currently on associated medication.

"We are expecting many of the trial participants to be men in their 50s and women in their 60s; though younger if they have several risk factors," added Professor Rodgers.

The pill is expected to cost about \$30 a year and is aimed at reducing the risk of heart disease and stroke in poor and rich countries. "The established risk factors cause 90 per cent of heart disease in rich and poor countries alike," said Professor Rodgers. "Both settings need more affordable, practicable solutions for chronic care and prevention."

The HRC has also funded a major trial that will assess the role of the polypill in people with established indications for treatment.

*The development of the heart pill was funded by The University of Auckland, the Health Research Council of New Zealand and other agencies. The heart pill trial is jointly funded by the Health Research Council of New Zealand and the Wellcome Trust of the UK.*



Professor Anthony Rodgers

#### Keywords:

- Cardiovascular risk, stroke, cholesterol, blood pressure

#### Key facts:

- Cardiovascular risk is measured through a combination of factors, including cholesterol and blood pressure levels, smoking, family history and being overweight
- The trial will assess the pill's tolerability and effects on blood pressure and cholesterol

#### Aims of this research:

- To create an inexpensive pill that will halve the risk of heart disease and stroke, in poor and rich countries
- To test whether patients with increased risk can be identified early, and safely reduce risk factors with a single daily tablet

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