

The Daily Telegraph (London)

May 26, 2011 Thursday

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Scotland

**The 10p pill that 'halves risk of heart disease'**

**BYLINE:** Stephen Adams

**SECTION:** NEWS; FRONT PAGE; Pg. 1

***Word Count = 484 (round to 480)***

***Sentence Count = 25 (including title)***

A 10P-A-DAY "polypill" containing aspirin and statins can halve the risk of **heart** disease and **stroke**, according to the world's first international trial of the drug.

Researchers found "sizeable reductions" in blood pressure and levels of "bad" cholesterol among those who took the polypill for 12 weeks.

Separate pills are prescribed to millions of people worldwide to lower their chances of **heart** attack and **stroke** but scientists believe a combined pill will encourage people to take the medications more reliably.

Cardiovascular disease is Britain's biggest killer, accounting for almost 200,000 deaths a year.

The first international polypill study, published today and part-funded by the Wellcome Trust, has suggested that a single pill could be extremely effective.

A research team examined data from 378 people with a raised risk of cardiovascular disease.

Half were given the polypill and half a placebo. The participants were British, Dutch and Indian.

The study found that both blood pressure and levels of "bad" cholesterol were reduced.

Systolic blood pressure was reduced from a pre-trial average of 134 mmHg - mmHg being the standard unit for measuring blood pressure - to 124.

Bad cholesterol came down from 3.7 millimoles per litre to 2.9.

It was calculated that the polypill would roughly halve the chance of a major cardiovascular event in those with a raised risk of disease.

Writing in the journal PLoS One, the researchers said that the benefits to those at a high risk would be even greater.

Prof Anthony **Rodgers**, of the George Institute for Global Health in Australia, who led the study, said: "The results show a halving in **heart** disease and **stroke** can be expected for people taking this polypill long-term.

We are really excited."

The combined pill contains 75mg aspirin, 20mg simvastatin, 10mg lisinopril and 12.5mg hydrochlorothiazide.

Aspirin prevents blood getting too "sticky", which can lead to clots that cause **heart** attacks; statins lower cholesterol; while the latter two drugs lower blood pressure.

Prof Simon Thom, of **Imperial** College London, said the Indian pharmaceutical firm Dr Reddys had committed to make the polypill "as dirt cheaply as possible".

About 17million people die of cardiovascular disease every year, 80 per cent of them in developing countries.

Prof Thom said in such countries the cost could be just £1.20 a month, with richer countries paying more.

Even so, the cost in Britain could be as low as £3 a month.

Prof **Rodgers** added that one of the hopes with a polypill is that it would help people take medicines long-term.

Dr Lorna Layward, from The **Stroke** Association, said combining medications into one pill could make taking the medication much simpler.

However, she said it was "extremely early days" and if it came to fruition patients should be treated on an individual basis as it might not be suitable for all.

A Department of Health spokesman said: "We welcome any evidence that contributes to providing the best treatment."

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The Express

May 26, 2011 Thursday

U.K. 1st Edition

**DAILY PILL TO SAVE MILLIONS**

**BYLINE:** By Victoria Fletcher Health Editor

**SECTION:** NEWS; 01

***Word Count = 677 (round to 680)***

***Sentence Count = 30 (including title)***

New miracle drug beats both cancer and **heart** disease

A NEW wonder pill that can halve the risk of **heart** disease and **strokes** will give hope to millions, a study claims today.

The single tablet, to be taken once a day, may also offer substantial protection against cancer.

Incredibly, the 'polypill', which combines aspirin, a statin, a blood pressure drug and a diuretic, could cost just 13p a day.

In Britain alone, it could lead to twice as many patients being offered preventative treatment for **heart** problems, while around the globe it could save millions of lives.

Cardiovascular disease is one of the biggest killers in the UK, claiming almost 200,000 lives a year.

Although the best way to avoid **heart** disease is to adopt a healthy lifestyle, doctors can also prescribe statins to reduce cholesterol and blood pressure pills to help hypertension.

Some patients are also told to take aspirin to thin their blood, while a water pill - or diuretic - can prevent water retention.

However, many patients find it inconvenient and confusing having to take four different pills every day, often at different times, leading some not to bother at all.

Now an international study suggests the new polypill - which could be available within two years - can offer the same benefits as the four separate drugs.

Importantly, the study also shows the four-in-one pill could increase the number of patients treated under current guidelines from five to ten per cent of the adult population.

Study leader Anthony **Rodgers,** professor of global health at the George Institute in Sydney, Australia, said: "We have to change our horizons and the number of diseases we look at when assessing cardiovascular risk.

"The results show a halving in **heart** disease and **stroke** can be expected for people taking the polypill long term.

We know from other trials that long term there would also be a 25 to 50 per cent lower death rate from colon cancer, plus reductions in other major cancers, **heart** failure and renal failure.

"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."

The latest study, published in the journal PLoS One, involved 378 patients from around the world.

All had an increased risk of **heart** problems but none were on medication because their individual readings for cholesterol or blood pressure were not high enough to qualify for medical intervention.

The study gave half of the participants the polypill for three months and the other half a dummy pill.

After 12 weeks, those who had taken the polypill had substantially reduced blood pressure and cholesterol levels.

The authors claim that within a few years of treatment the pill would halve the risk of **heart** disease or a **stroke**.

The polypill contains 75mg of aspirin, 10mg of the blood pressure agent lisinopril, 12.5mg of the diuretic hydrochlorothiazide, and 20mg of simvastatin, a cholesterol medicine.

Although aspirin can cause internal bleeding in some patients, the authors believe its role in preventing cancer outweighs such risks.

However, the study also showed that one in 20 patients suffered such bad side effects that they stopped taking the medication.

For this reason, the authors say the polypill should only be offered to patients at risk of **heart** disease rather than to everyone over a certain age.

Professor Simon Thom, of **Imperial** College London, who led the UK arm of the trial, said: "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."

Last night, charities welcomed the report but said larger studies were needed.

Dr Lorna Layward, spokeswoman for the **Stroke** Association said: "Combining the pills into one could make taking the medication much simpler.

"However, it's important to note this pill might not be suitable for everyone and it may have side effects.

"It's also extremely early days and a lot more research needs to be carried out into this pill to ensure its safety."

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The Guardian (London) - Final Edition

May 26, 2011 Thursday

**Scientists hail the single pill that halves the risk of heart disease: Once-a-day polypill will tackle chronic diseases Good results from first international trials**

**BYLINE:** Sarah Boseley Health editor

**SECTION:** GUARDIAN HOME PAGES; Pg. 12

***Word Count = 826 (round to 830)***

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A once-a-day tablet containing four common drugs to lower cholesterol and blood pressure has been shown to halve the risk of **heart** disease and **stroke** in those who take it, opening the way to a simple form of global mass preventative medication.

The polypill has been a gleam in scientists' eyes for more than a decade.

In 2001, the World Health Organisation and the Wellcome Trust - which funded the trial - convened a meeting to discuss the possibility of producing a single combination pill which would be a potent weapon in the battle against chronic diseases.

A single pill, the meeting concluded, would make it more likely that those at risk of **heart** disease, **stroke** or diabetes would stick to their medication and would be much cheaper than taking several drugs.

Results from the first international trial of a polypill containing drugs to lower cholesterol and blood pressure - and also aspirin - show that it could make a major difference to the toll of chronic disease, even though they are not as good as the original polypill pioneers hoped.

Professors Sir Nicholas Wald and Malcolm Law, in a seminal article in 2003, anticipated that the polypill could cut the risk of **heart** disease and **strokes** by 80% with few side-effects.

In practice, in the trial which took place in the UK, Australia, Brazil, India, New Zealand, the Netherlands and the US, reported in the open access journal PLoS One, the predicted risk was cut by 50%, not 80%.

And there were more side-effects than expected, affecting about one in six of those who took part in the trial.

Most of the side-effects were mild but about one participant in 20 stopped taking the polypill as a result.

Professor Anthony **Rodgers** of the George Institute for Global Health, who led the trial, said he thought the results were "more realistic than the original hope, which I think now people are realising was more like hype".

He described the results as "very good, but not the panacea it was originally thought to be".

Most side-effects were caused by the aspirin in the pill, which is known to cause gastric bleeding in some people.

But aspirin has also been shown to cut the risk of cancer, which gives the polypill a further dimension.

"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," said **Rodgers**.

The polypill could be most suitable for those people who have already suffered a **heart** attack or **stroke** and are therefore at risk of another one.

They would normally be put on a cocktail of pills but some might be more likely to stick to medication if only required to take one a day.

The other group likely to be offered it are those who are at risk because they are clearly overweight or have high blood pressure and cholesterol readings.

At one time it was thought that everybody over the age of 55 should be offered the polypill, but the side-effects make that unlikely.

The main value in the UK would be in encouraging adherence to medication, but in the developing world, where other trials are going on, the low cost may be a significant issue.

Professor Simon Thom of **Imperial** College, London, who led the UK arm of the trial, said the Indian company making the polypill, which it calls the Red **Heart** pill, is aiming for a price in India of £13 per patient per year.

"We anticipate the cost being somewhat more in developed countries.

The poorer countries will be subsidised by the surcharge in the wealthier countries," he said.

Natasha Stewart, senior cardiac nurse at the British **Heart** Foundation, said: "While the concept of taking one pill rather than many sounds appealing, this was a small study and we'd need to see results from much larger trials to determine the validity of its potential benefits.

While medicines could help to reduce risk, they're not a substitute for living a healthy lifestyle, which will always remain a vital part of keeping your **heart** in good shape."

Dr Lorna Layward, from the **Stroke** Association, said: "Anyone at risk of **stroke** should be supported in reducing their risk through lifestyle changes and medication.

Many people with high blood pressure and high cholesterol are required to take multiple pills every day in order to reduce their risk.

Calculating when each pill needs to be taken can often be confusing and so combining the pills into one could make taking the medication much simpler.

"However, it's important to note that this pill might not be suitable for everyone and it may have side-effects so every patient should be assessed and treated on an individual basis.

The polypill will be available in the UK within a couple of years after it has gone through regulatory approval, the scientists expect, but sooner in India.

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The Scotsman

May 26, 2011, Thursday

1 Edition

**The pill to cure (almost) every ill**

**BYLINE:** Lyndsay Buckland Health Correspondent

**SECTION:** Pg. 8

***Word Count = 814 (round to 810)***

***Sentence Count = 40 (including title)***

Taking a "polypill" which combines four different drugs can cut people's risk of **heart** disease and **stroke** by half, the world's first international trial of the treatment has found.

The capsule, which contains aspirin and drugs to lower cholesterol and blood pressure, could potentially revolutionise the care of patients at risk of serious illness.

Similar treatments have also been shown to cut cancers and kidney disease.

But campaigners in Scotland warned people should not see the pill as an alternative to improving their diet and taking more exercise.

At present, separate pills are prescribed to millions of people worldwide to lower the chances of **heart** attack and **stroke**.

But for many years, researchers have been investigating the prospect of a combined pill, with some suggesting it could even be taken by everyone over the age of 55 to cut the risk of disease.

Many also believe that combining the medications in one pill could make it easier for people to take and stick with.

In the latest study, published in the journal Public Library of Science One, experts tested the pill in 378 people in countries including the UK and US who did not already need any of its components, but who had more than a 7.5 per cent estimated risk of cardiovascular disease.

The drug contained 75mg of aspirin, the two blood pressure drugs lisinopril (10mg) and hydrochlorothiazide (12.5mg), and 20mg of the cholesterol-lowering drug simvastatin.

After 12 weeks, experts analysed the effect of the drug on blood pressure and cholesterol, and how well it was tolerated.

It did cause side-effects, including stomach irritation and coughs, in about one in six people, and some participants stopped taking the treatment because of this.

But overall, the study found the risk of **heart** disease and **stroke** was significantly reduced.

Professor Anthony **Rodgers**, of the George Institute for Global Health, said: "The results show a halving in **heart** disease and **stroke** can be expected for people taking this polypill long-term.

"We know from other trials that long term there would also be a 25-50 per cent lower death rate from colon cancer, plus reductions in other major cancers, **heart** failure and renal failure.

"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."

Prof **Rodgers** said a polypill could be available in the UK in as little as one to two years.

The cost could be as low as GBP2 a month per patient.

"There are large numbers of people who could potentially benefit," he said.

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

Louise Peardon, of charity Chest, **Heart and Stroke** Scotland, said they would prefer people took action to live healthier lifestyles.

"Things like the polypill are a good idea, but the concerns would be around medicalising risk factors," she said.

"Our approach would be on the side of encouraging lifestyle changes first."

Andy Carver, of British **Heart** Foundation Scotland, added: "While the concept of taking one pill rather than many sounds appealing, this was a small study and we'd need to see results from much larger trials.

"Medicines are not a substitute for a healthy lifestyle."

Recipe for health

What is in the polypill and what does it do?

Aspirin 75mg

A low dose of aspirin, to reduce the risk of **heart** attack and **stroke**.

Research also shows aspirin can reduce risk of cancer in the long term, including colon cancer, and also cancer of the prostate, lung and oesophagus.

The effects on cancer can be seen after five years of use.

Lisinopril 10mg and Hydrochlorothiazide 12.5mg

Two different types of drugs to lower blood pressure are used, because research shows it is better to use a low to medium dose of two drugs rather than a high dose of one drug.

This allows for a good reduction in blood pressure, with few side effects.

Having high blood pressure puts extra strain on the **heart** and blood vessels, which can increase the risk of **heart** attack and **stroke**.

High blood pressure can also cause **heart** and kidney disease, and has been linked to some forms of dementia.

Simvastatin 20mg

A member of the group of drugs called statins, which are commonly used to lower cholesterol levels.

Evidence strongly shows that high cholesterol levels can cause narrowing of the arteries - known as atherosclerosis - leading to **heart** attack and **stroke**.

This is because cholesterol can build up in the artery wall and restrict the flow of blood to the **heart,** brain and the rest of the body.

It also increases the chance of a blood clot developing.

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**TELEGRAPH**

**10p polypill 'halves heart disease and stroke risk'**

By [Stephen Adams](http://www.telegraph.co.uk/journalists/stephen-adams/), Medical Correspondent

6:30AM BST 26 May 2011

**A new 10p-a-day ‘polypill’ containing aspirin and statins halves the risk of heart disease and stroke, according to the world’s first international trial of the drug.**

A research team found "sizeable reductions" in blood pressure and levels of 'bad' LDL cholesterol among those who took the polypill over 12 weeks, compared to those who took a placebo.

Separate pills are already prescribed to millions of people worldwide to lower their chances of heart attack and stroke.

But scientists have been looking at the prospect of a combined pill, which they believe will encourage more people to take the medications more reliably.

Eight years ago [Prof Sir Nichlas Wald, who demonstrated that passive smoking causes cancer](http://www.wolfson.qmul.ac.uk/epm/staff/profile/wald_n.html), proposed the polypill [in an article in the British Medical Journal](http://www.bmj.com/content/326/7404/1419.full).

He wrote that such an easy-to-take pill could significantly reduce the burden of cardiovascular disease, which is Britain's biggest killer, accounting for almost 200,000 deaths a year.

Taking such a preventive pill should be as automatic as "brushing your teeth", he later suggested.

Now [the first international polypill study](http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0019857), published last night and part funded by the Wellcome Trust, has suggested it could be extremely effective.

The researchers examined data from 378 people with a raised risk of cardiovascular disease. Half were given the polypill and half the placebo.

About a third of the participants were British, a third Dutch and a third Indian.

Specifically, systolic blood pressure was reduced from a pre-trial average of 134 mmHg to 124; while 'bad' LDL cholesterol came down from 3.7 mmol/L to 2.9.

Doctors use mmHg as a standard unit for measuring blood pressure, while mmol/L - millimoles per litre - is used as a measurement unit for very low concentrations of substances in blood.

Cardiologists know that having high blood pressure and cholesterol raises the chances of cardiovascular events, and are able to estimate how much reducing these factors decreases that risk.

The researchers calculated that the polypill would roughly halve the incidence of major cardiovascular events in people with similar risk profiles to the participants.

Writing in the journal *Public Library of Science One,* they concluded that the benefits to those at a high risk would be even greater: "Overall about one in four high risk people would be predicted to avoid a major event over five years."

Prof Anthony Rodgers of the George Institute for Global Health in Australia, who led the study, said: "The results show a halving in heart disease and stroke can be expected for people taking this polypill long-term.

"We are really excited about this - it is a step closer to providing the polypill to patients."

It has long been known that taking aspirin and statins separately reduces the risk of cardiovascular disease, but this is one of the first studies examining taking them in a combined pill.

It contains 75mg aspirin, 20mg simvastatin, 10mg lisinopril and 12.5mg hydrochlorothiazide.

Aspirin prevents blood getting too 'sticky', which can lead to clots that cause heart attacks; statins lower cholesterol; while the latter two drugs lower blood pressure.

There were fears that the drugs could react in a pill while being stored, and cancel each other out, but the trial proved these were unfounded.

All four drugs are off-patent, meaning any drugs company can manufacture them.

Prof Simon Thom, of Imperial College London, said the Indian pharmaceutical firm Dr Reddys had committed to make the polypill "as dirt cheaply as possible".

The cost issue is particularly important in poorer and middle income countries, which are facing growing epidemics of 'lifestyle' diseases due to changing diets and people getting less exercise.

About 17 million people die of cardiovascular disease every year, 80 per cent of them in developing countries.

Prof Thom said in such countries the cost could be just £1.20 a month, with richer countries which were able to shoulder the economic burden paying more. Even so, the cost in Britain could be as low as £3 a month.

The case for the polypill has been given a powerful boost by British-led research, [published in The Lancet last winter](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)62110-1/abstract), showing that regularly taking low-dose aspirin reduces the risk of certain cancers, including bowel cancer, by up to 50 per cent.

Prof Rodgers commented: "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."

This polypill is likely to be available in India soon.

However, the Department of Health is more cautious.

Two years ago Prof Roger Boyle, England's heart disease 'czar', told MPs that he liked the "concept" but there were questions marks over safety.

He also said there was a "fine line" between preventive medicine and "medicalising" the population.

Side effects are a big issue.

Aspirin is known to aggravate the intestine and can cause internal bleeding, although most cases are minor.

This trial found that about one in 20 people stopped taking the polypill because of side effects, mainly due to such bleeding but also due to light-headedness caused by too low blood pressure.

Prof Rodgers said it was highly unlikely that all middle aged and elderly people would be offered a polypill in the future, but that it could be allocated to those with a higher risk of heart disease, stroke and certain cancers.

That could feasibly be one in five people over 30, perhaps more.

Prof Thom, who led the UK arm of the trial, said: "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."

Dr Lorna Layward, from The Stroke Association, said: "Many people with high blood pressure and high cholesterol are required to take multiple pills every day in order to reduce their risk.

"Calculating when each pill needs to be taken can often be confusing and so combining the pills into one could make taking the medication much simpler.

"However, it's important to note that this pill might not be suitable for everyone and it may have side effects so every patient should be assessed and treated on an individual basis.

It's also extremely early days and a lot more research needs to be carried into this pill to ensure its safety."

A Department of Health spokesman said: "We welcome any evidence that contributes to providing the best treatment for people with cardiovascular disease."

He added: "It is also important to remember that changes made to a person's lifestyle such as stopping smoking, eating healthily and taking regular exercise have far reaching health benefits that will not be reaped from medication, including reduction in the risk of developing diabetes and cancer."