Adherencia terapéutica: influencia de la crisis y nuevas alternativas terapéuticas

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ADHERENCIA VS CUMPLIMIENTO

ADHERENCIA

Grado en el que la conducta de un paciente,
en relación con la toma de la medicación,
el seguimiento de una dieta o la modificación de hábitos
de vida se corresponde con las recomendaciones
acordadas con el profesional sanitario.

ADHERENCIA VS CUMPLIMIENTO

CUMPLIMIENTO

Implica una conducta de sumisión y obediencia a una orden, propia de una relación paternalista entre los profesionales de la salud y el paciente**.**

ADHERENCIA

" Drugs don’t work
in patients
who do not take them.”

"No
medication
works
inside a
bottle .”

– C. Everett Koop, former US Surgeon General 1981-1989

ADHERENCIA TERAPÉUTICA DESPUÉS DE UN IAM

1 mes
después de padecer un IAM

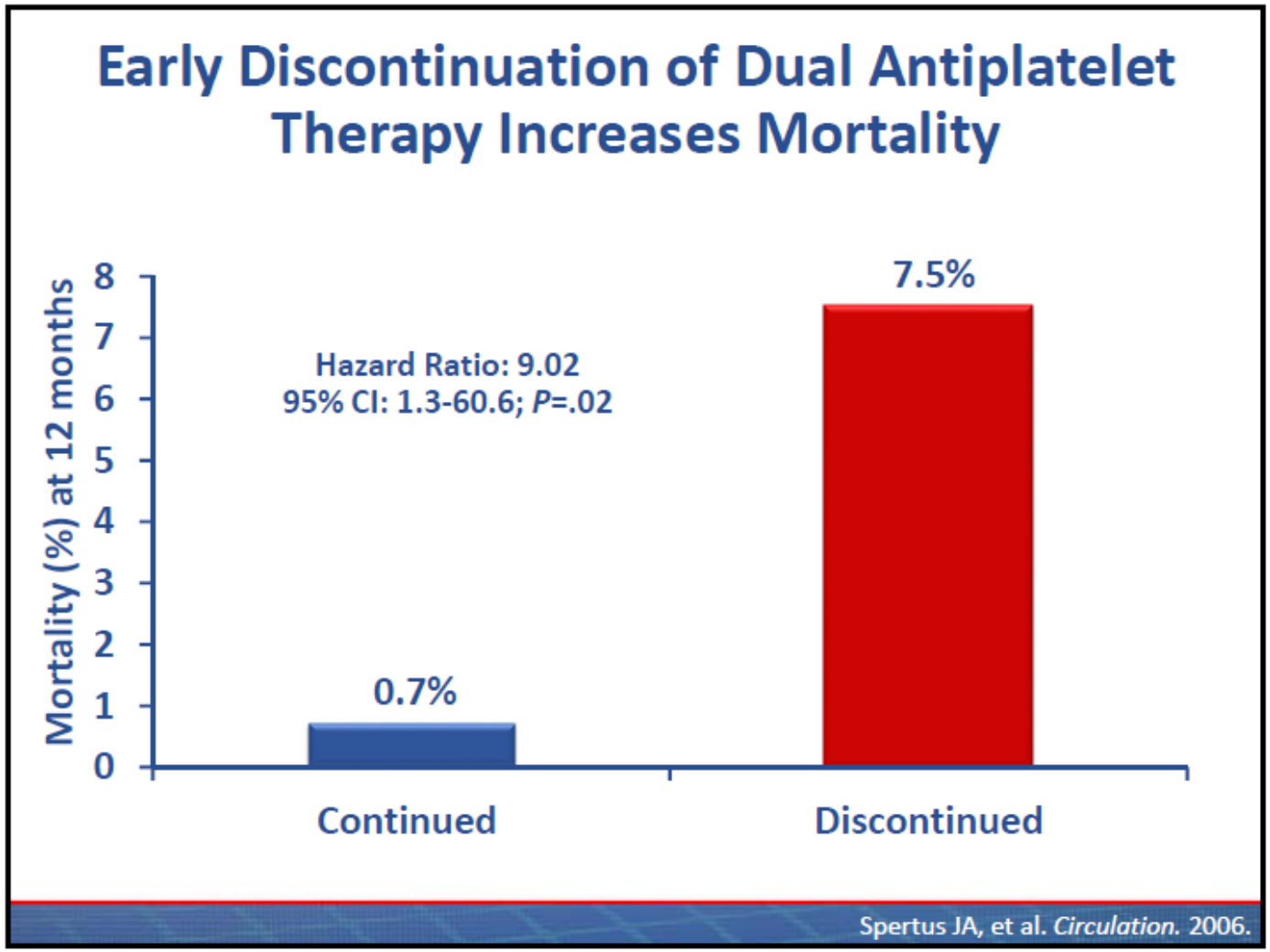
25-30% de los pacientes dejan de tomar algunos de los fármacos prescritos

1 año
después de padecer un IAM

50% de los pacientes persisten con estatinas, betabloqueantes, o antihipertensivos

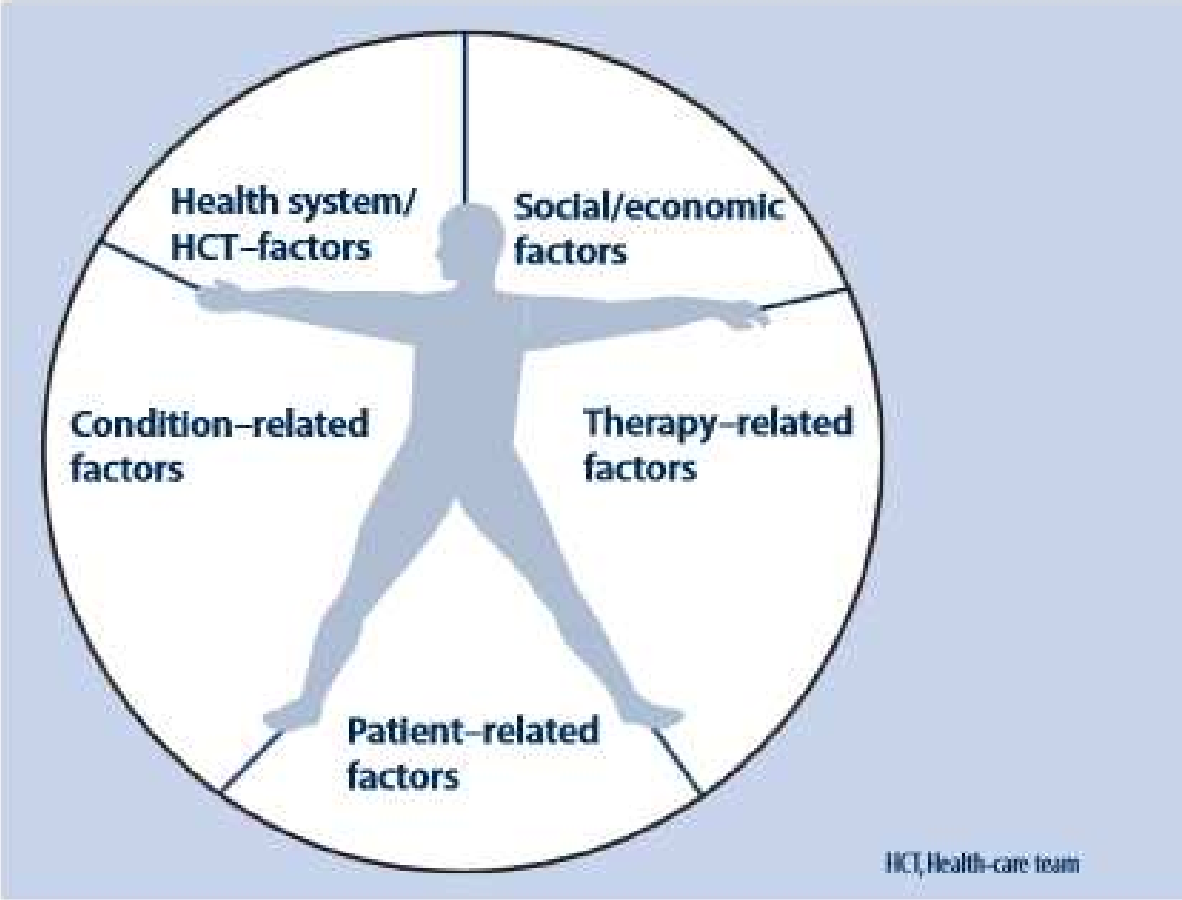
Ho PM, Circulation. 2009;119(23):3028-35.
Osterberg L, NEJM 2005;353(5):487-97.

CONSECUENCIAS CLÍNICAS DE LA NO ADHERENCIA



Las 5 dimensiones de la adherencia

Figure 3 The five dimensions of adherence



Crisis: Patients not taking their medications USAToday Oct 15,2013



Altonya Sheppard, 37, of Philadelphia, PA, is uninsured and doesn't think the insurance she'll be able to get in the health insurance marketplace will be either affordable or cover enough of her multiple medications.(Photo: Eileen Blass USAToday Oct 15, 2013)

Impacto de la crisis económica y las huelgas de farmacias en Grecia



Quality in Primary Care (2014) 22 (5): 238-44

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Research papers

Impact of the financial crisis on adherence to treatment of a rural population in Crete, Greece

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ABSTRACT

Background The global economic crisis has affected Greece. Data on patients' adherence to medications for chronic diseases are missing. The objective of this study was to identify to what extent the financial crisis and the repeated pharmacists strike have influenced patients adherence to therapy.

Method:

Design A quantitative and qualitative study in rural Crete was designed and implemented in February 2013 with the use of a pretested questionnaire with opened and closed questions.

Setting Rural practices in a well-defined geographical area of Crete.

Subject The questionnaire was addressed in all patients that visited the rural practices with chronic or acute diseases for two consecutive weeks.

Main Outcome(s) and Measure(s) Age, annual income, adherence to therapy, patient's views and feelings.

Results: 288 patients participated. The mean age was 68+6.87. The majority of the patients have lowered the doses of several medications by themselves as they weren't able to afford the cost je; all patients receiving insulin had lowered the dosages; 46.42% of patients with COPD or asthma had stopped their medications completely, decreased dosages or used similar medications that had in the past; patients with dislipidaemia received their medications as suggested only in 51.8%. Patients with cardiovascular diseases received their medications as suggested in 75.6% while the rest have diminished or skipped dosages. Most common emotions reported were those of sadness, fear, stress, anxiety and isolation.

Conclusions The economic crisis has influenced patients' adherence to therapy in rural areas as well as their psychological and emotional status. There is an urgent need for action within the context of primary care.

Keywords: adherance, financial crisis



Impacto de la crisis económica y las huelgas de farmacias en Grecia

All patients that visited the rural practices with chronic or acute diseases for two consecutive weeks (n 288)

- *42% of patients with COPD or asthma had stopped their medications completely, decreased dosages or used similar medications that had in the past.*
- *Patients with dyslipidemia received their medications as suggested only in 51.8%.*
- *Patients with cardiovascular diseases received their medications as suggested in 75.6% while the rest have dismissed or skipped dosages.*

Quality in Primary Care (2014) 22 (5): 238-44

Decline of the Mediterranean diet at a time of economic crisis. Results from the Moli-sani study.



Cross-sectional analysis in a population-based cohort study which randomly recruited 21,001 southern Italian citizens

— Bonaccio M. Nutr Metab Cardiovasc Dis. 2014 Mar 1.



Decline of the Mediterranean diet at a time of economic crisis. Results from the Moli-sani study.

Highest prevalence of adherence to MD was observed during the years 2005-2006 (31.3%) while the prevalence dramatically fell down in the years 2007-2010 (18.3%; P<0.0001).

The decrease was stronger in the elderly, less affluent groups, and among those living in urban areas.

Both wealth score and education were major determinants of high adherence to MD with 31% (95%CI: 18-46%) higher adherence to this pattern within the wealthier group compared to the less affluent category.

— Bonaccio M. Nutr Metab Cardiovasc Dis. 2014 Mar 1.

- Doctor, can I take the so called Polypill to prevent and MI in the future?



Polypill

The Polypill strategy, based on a single daily pill containing six components would prevent 88% of heart attacks and 80% of strokes in healthy individuals aged 55 and older .

—— Wald, Law. BMJ VOLUME 326 28 JUNE 2003 bmj.com

Ensayos clínicos realizados con la Polypill (al menos una estatina + antihipetensivo)

13 ECC con un total de 8,898 participantes.

7 de los 13 ensayos se evaluaron en prevención primaria.

Ninguno de estos ensayos ha demostrado una reducción de la morbimortalidad (tampoco estaban diseñados para ello)

Huffman MD (2015) The Polypill: From Promise to Pragmatism. PLoS Med 12(8): e1001862. doi:10.1371/journal.pmed.1001862
http://journals.plos.org/plosmedicine/article?id=info:doi/10.1371/journal.pmed.1001862

Differences in adherence between the intervention and control groups in fixed-dose combination therapy trials that report adherence

fixed-dose combination increased adherence by **44%** compared with usual care in patients with prevalent cardiovascular disease or high risk for cardiovascular disease

	Fixed-Dose Combination Therapy		Comparator			
Study	**Events**	**Total**	**Events**	**Total**	**Weight**	**Relative Risk (95% CI)**
UMPIRE 2013 [6]	829	1,002	621	1,002	31.0%	1.33 (1.26, 1.41)
IMPACT 2014 [9]	208	256	119	257	23.8%	1.75 (1.52, 2.03)
Kanyini GAP 2014 [8]	213	311	143	312	23.9%	1.49 (1.30, 1.72)
FOCUS 2014 [7]	169	350	133	345	21.3%	1.25 (1.05, 1.49)
Overall	**1,419**	**1,919**	**1,016**	**1,916**	**100%**	**1.44 (1.26, 1.65)**

Abbreviations: FOCUS, Fixed-Dose Combination Drug for Secondary Cardiovascular Prevention; IMPACT, IMProving Adherence using Combination Therapy; MI-FREE, Post-Myocardial Infarction Free Rx Event and Economic Evaluation; UMPIRE, Use of a Multidrug Pill In Reducing Cardiovascular Events

doi:10.1371/journal.pmed.1001862.t001

Huffman MD (2015) The Polypill: From Promise to Pragmatism. PLoS Med 12(8): e1001862. doi:10.1371/journal.pmed.1001862
http://journals.plos.org/plosmedicine/article?id=info:doi/10.1371/journal.pmed.1001862

Manufacturers and regulatory status of fixed-dose combinations for cardiovascular disease prevention

Manufacturer	Combination	Current Regulatory Status
Ferrer Internacional, Spain	Trinomia (aspirin 100 mg + ramipril 2.5 mg, 5 mg, or 10 mg + simvastatin 40 mg or atorvastatin 20 mg)	Simvastatin version: Argentina, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, and México. Atorvastatin version: Austria, Belgium, Bulgaria, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Poland, Portugal, Romania, Spain, and Sweden
Cadila Pharmaceuticals, India	Polycap (aspirin 100 mg + ramipril 5 mg + atenolol 50 mg + hydrochlorothiazide 12.5 mg + simvastatin 20 mg)	India and Zambia
Cipla, India	Aspirin 75 mg + losartan 50 mg + atenolol 50 mg + atorvastatin 10 mg. Aspirin 75 mg + losartan 25 mg + amlodipine 2.5 mg + atenolol 50 mg + simvastatin 40 mg for the polypill investigators (7)	India
Dr. Reddy's Laboratory India (License held by the George Institute for Global Health)	Red Heart Pill 1 (aspirin 100 mg + lisinopril 10 mg + atenolol 50 mg + simvastatin 40 mg). Red Heart Pill 2 (aspirin 100 mg + lisinopril 10 mg + hydrochlorothiazide 12.5 mg + atenolol 50 mg + simvastatin 40 mg)	Not currently available

doi:10.1371/journal.pmed.1001862.t002

Huffman MD (2015) The Polypill: From Promise to Pragmatism. PLoS Med 12(8): e1001862. doi:10.1371/journal.pmed.1001862
http://journals.plos.org/plosmedicine/article?id=info:doi/10.1371/journal.pmed.1001862

Argumentos a favor de la Polypill

A favor

Mejor adherencia al tratamiento

- Reducción de la complejidad terapéutica en paciente polimedicados
- Mayor facilidad en la prescripción

Menor coste

- Mayor disponibilidad del medicamento en países en desarrollo
- Menor coste por la reducción de eventos cardiovasculares al mejorar la adherencia y la prevención

Author: Sanz G, et al. Policomprimido: ¿quimera o realidad? Rev Esp Cardiol. 2014.

Argumentos en contra de la Polypill

En contra

- ***En prevención primaria***

  - Ausencia de estudios que prueben su eficacia y la aceptación de pacientes y profesionales.
  - Dificultad en la selección de fármacos y dosis.
  - Dificultad para identificar a los pacientes adecuados (indicación) y el nivel de riesgo requerido para iniciar la terapia.
  - Efecto negativo en los estilos sida saludables.

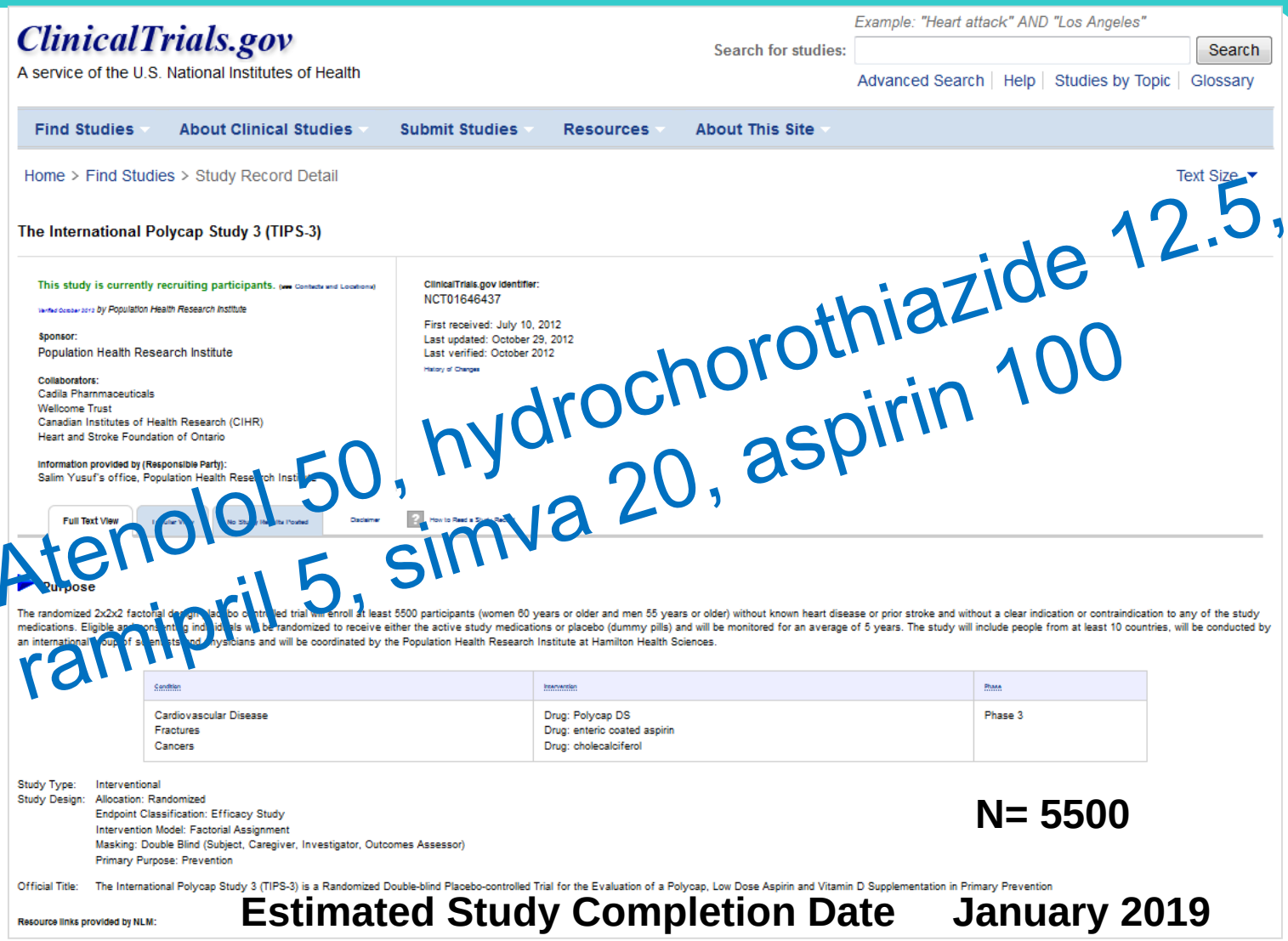
- ***En prevención secundaria***

  - Dificultad en individualizar las dosis y alcanzar las recomendadas por las guías.

Polypill

Ensayos clínicos en marcha en prevención primaria

Ensayos Clínicos en marcha en Prevención Primaria: TIPS3



ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

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Home > Find Studies > Study Record Detail

Text Size

The International Polycap Study 3 (TIPS-3)

This study is currently recruiting participants.

Verified October 2012 by Population Health Research Institute

Sponsor:
Population Health Research Institute

Collaborators:
Cadila Pharmaceuticals
Wellcome Trust
Canadian Institutes of Health Research (CIHR)
Heart and Stroke Foundation of Ontario

Information provided by (Responsible Party):
Salim Yusuf's office, Population Health Research Institute

ClinicalTrials.gov Identifier:
NCT01646437

First received: July 10, 2012
Last updated: October 29, 2012
Last verified: October 2012

History of Changes

Full Text View

Purpose

The randomized 2x2x2 factorial design, placebo controlled trial will enroll at least 5500 participants (women 60 years or older and men 55 years or older) without known heart disease or prior stroke and without a clear indication or contraindication to any of the study medications. Eligible and consenting individuals will be randomized to receive either the active study medications or placebo (dummy pills) and will be monitored for an average of 5 years. The study will include people from at least 10 countries, will be conducted by an international group of scientists and physicians and will be coordinated by the Population Health Research Institute at Hamilton Health Sciences.

Condition	Intervention	Phase
Cardiovascular Disease Fractures Cancers	Drug: Polycap DS Drug: enteric coated aspirin Drug: cholecalciferol	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Factorial Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Prevention

Official Title: The International Polycap Study 3 (TIPS-3) is a Randomized Double-blind Placebo-controlled Trial for the Evaluation of a Polycap, Low Dose Aspirin and Vitamin D Supplementation in Primary Prevention

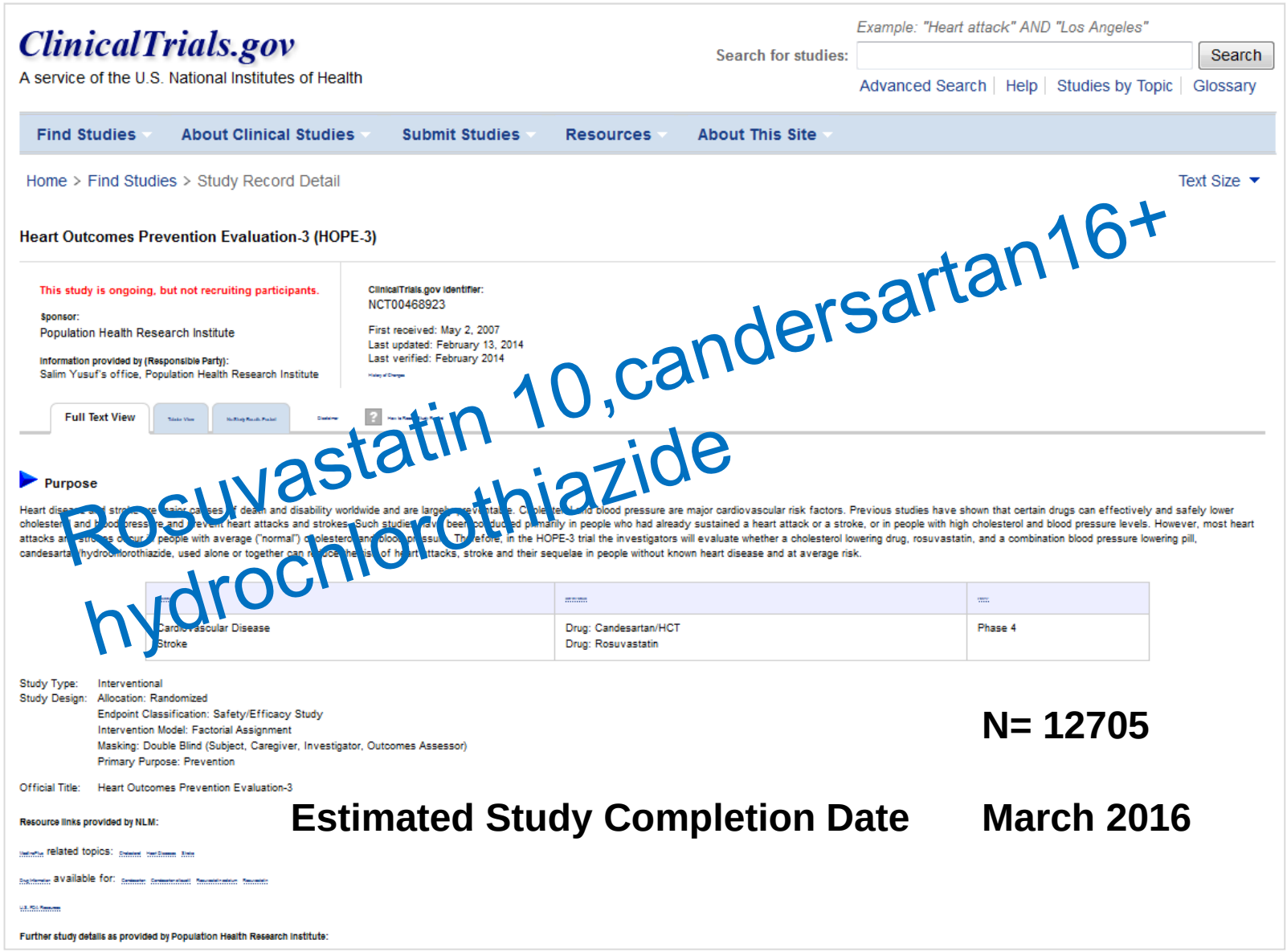
Resource links provided by NLM:

Atenolol 50, hydrochorothiazide 12.5, ramipril 5, simva 20, aspirin 100

N= 5500

Estimated Study Completion Date January 2019

Ensayos Clínicos en marcha en Prevención Primaria: HOPE-3



ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"

Search for studies: Search

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Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Study Record Detail

Text Size

Heart Outcomes Prevention Evaluation-3 (HOPE-3)

This study is ongoing, but not recruiting participants.

Sponsor:
Population Health Research Institute

Information provided by (Responsible Party):
Salim Yusuf's office, Population Health Research Institute

ClinicalTrials.gov Identifier:
NCT00468923

First received: May 2, 2007
Last updated: February 13, 2014
Last verified: February 2014

Full Text View

Posuvastatin 10,candersartan16+ hydrochlorothiazide

Purpose

Heart disease and stroke are major causes of death and disability worldwide and are largely preventable. Cholesterol and blood pressure are major cardiovascular risk factors. Previous studies have shown that certain drugs can effectively and safely lower cholesterol and blood pressure and prevent heart attacks and strokes. Such studies have been conducted primarily in people who had already sustained a heart attack or a stroke, or in people with high cholesterol and blood pressure levels. However, most heart attacks and strokes occur in people with average ("normal") cholesterol and blood pressure. Therefore, in the HOPE-3 trial the investigators will evaluate whether a cholesterol lowering drug, rosuvastatin, and a combination blood pressure lowering pill, candesartan/hydrochlorothiazide, used alone or together can reduce the risk of heart attacks, stroke and their sequelae in people without known heart disease and at average risk.

Cardiovascular Disease Stroke	Drug: Candesartan/HCT Drug: Rosuvastatin	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Factorial Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Prevention

Official Title: Heart Outcomes Prevention Evaluation-3

N= 12705

Estimated Study Completion Date **March 2016**

Resource links provided by NLM:

related topics:

available for:

Further study details as provided by Population Health Research Institute:

Ensayos Clínicos en marcha en Prevención Primaria: Poly-Iran



N= 7000

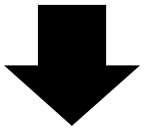
Estimated Study Completion Date April 2018

Conclusiones de la **Polypill**

- No está recomendado de forma masiva a toda la población.
- No hay evidencia para su utlización en prevención primaria.
- Se podría recomendar en algunos pacientes en prevención secundaria para mejorar la adherencia.

Conclusiones

- Los profesionales de la salud deben evaluar la adherencia a la medicación.
- Identificar razones de no adherencia.
- Promover la adherencia:



Conclusiones

- Consejos claros sobre beneficios y efectos adversos de la medicación.
- Considerar los hábitos y preferencias de los pacientes.
- Simplificación de los tratamientos
- Apoyo de enfermería/farmacéuticos/familiares
- Utilización de nuevas tecnologías (móbiles, apps, relojes con alarmas…)

Muchas gracias!