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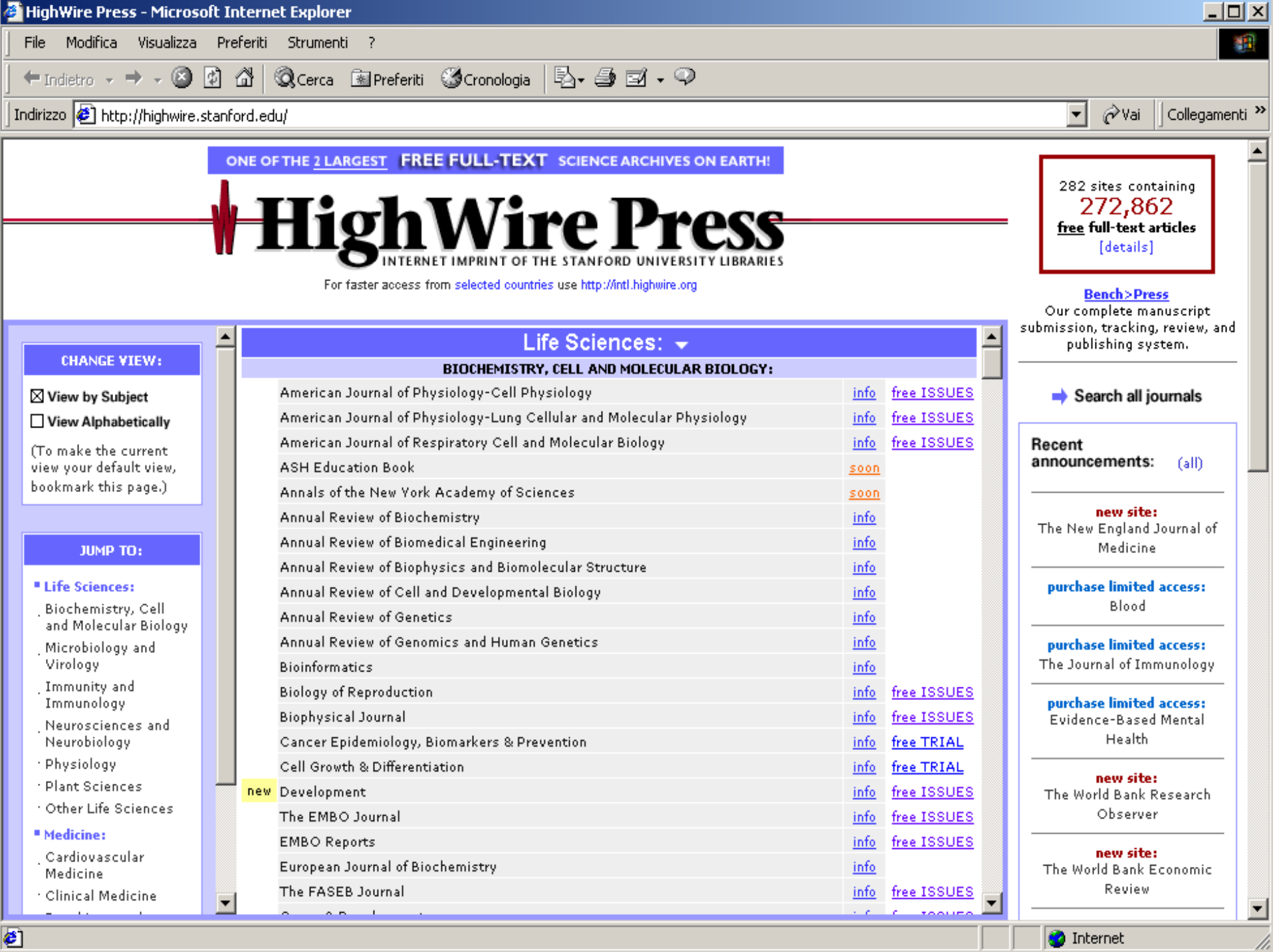
Bologna, 23 Novembre 2001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BMJ 2001;322:1087-1088 (5 May)

Papers

Analysis of prevalence of HIV-1 drug resistance in primary infections in the United Kingdom

Editorial by Little

UK Collaborative Group on Monitoring the Transmission of HIV Drug Resistance.

Correspondence to: D Pillay, PHLS Antiviral Susceptibility Reference Unit, Division of Immunity and Infection, University of Birmingham Medical School, Edgbaston, Birmingham B15 2TT
d.pillay@bham.ac.uk

Abstract

Objectives: To identify changes since 1994 in the prevalence of resistance to anti-HIV drugs in primary HIV-1 infections in the United Kingdom.

Design: Retrospective and prospective assessment of viruses obtained from people recently infected with HIV.

Setting: Multiple centres (patients enrolled in the UK register of seroconverters) and a single large HIV clinic (active case ascertainment).

Participants: 69 patients infected with HIV between June 1994 and August 2000.

Main outcome measures: Prevalence of key mutations associated with drug resistance in the reverse transcriptase and protease genes of HIV-1, by

This article has been cited by other articles:

- Little, S. J (2001). Is transmitted drug resistance in HIV on the rise?. *BMJ* 322: 1074-1075 [Full text]

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Read all Rapid Response responses

Analysis of prevalence of HIV-1 drug resistance in primary infections
Dr Sarah Fidler, Dr John Frater, Lecturer in HIV , *St. Mary's Hospital, Paddington, London*
bmj.com, 22 May 2001 [Response]

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Is transmitted drug resistance in HIV on the rise?.
Susan J Little
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American Heart Association. Fighting Heart Disease and Stroke

Published online before print November 15, 2001
(*Circulation Research* 2001, 10.1161/hh2401.101909)

Submitted on June 4, 2001
Revised on October 31, 2001
Accepted on November 1, 2001

Modulation of Endothelial Cell Growth Arrest and Apoptosis by Vascular Endothelial Growth Inhibitor

Jingyi Yu , Song Tian , Linda Metheny-Barlow , Li-Jin Chew , Andrew J. Hayes , Hongguang Pan , Guo-Liang Yu , and Lu-Yuan Li *

From the Department of Oncology (J.Y., S.T., L.M.-B., L.-J.C., A.J.H., H.P., L.-Y.L.), Georgetown University Medical Center, Washington, DC, and Mendel Biotechnology (G.-L.Y.), Hayward, Calif.

* To whom correspondence should be addressed. E-mail: lilu@georgetown.edu.

Vascular endothelial growth inhibitor (VEGI), a new member of the tumor necrosis factor family, is an endothelial-specific gene and a potent inhibitor of endothelial cell proliferation, angiogenesis, and tumor growth. We report here that VEGI mediates the following two activities in endothelial cells: early G_1 arrest in G_0/G_1 cells responding to growth stimuli, and programmed death in proliferating cells. G_0/G_1-synchronized bovine aortic endothelial cells were treated with VEGI before and after the onset of the growth cycle. When the cells were stimulated with growth conditions but treated simultaneously with VEGI, a reversible, early-G_1 growth arrest occurred, evidenced by the lack of late G_1 markers such as hyperphosphorylation of the retinoblastoma gene product and upregulation of the *c-myc* gene. Additionally, VEGI treatment led to inhibition of the activities of cyclin-dependent kinases CDK2, CDK4, and CDK6. In contrast, VEGI treatment of cells that had entered the growth cycle resulted in apoptotic cell death, as evidenced by terminal deoxytransferase labeling of fragmented DNA, caspase 3 activation, and annexin V staining, all of which were lacking in nonproliferating cells treated with VEGI. Additionally, stress-signaling proteins p38 and JNK were not as fully activated by VEGI in quiescent as compared with proliferating populations. These findings suggest a dual role for VEGI, the maintenance of growth arrest and induction of apoptosis, in the modulation of the endothelial cell cycle.

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☐ Pedro H.P.A. Schildknecht and Benedicto C. Vidal
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☐ Ian Harvey and Jenny L Donovan
Reporting on sexual function in randomised controlled trials
clinmed/2001090001 [Abstract] [Full Text]

☐ Nadiya Branicka, Ulyana Lushchyk, and Victor Novyckyy
Mathematical simulation of hemodynamical processes and medical technologies
clinmed/2001060002 [Abstract] [Full Text]

☐ Joan Agusto Cotin, Joan Lorentin Cotin, and Lizia Dalia

clinmed/2001060002v1 (August 2, 2001)

Mathematical simulation of hemodynamical processes and medical technologies

Nadiya Tsitsyura, Victor V. Novyc'kyy, Prof., Ph. D., Ulyana B. Lushchyk, MD.

Istyna Scientific Methodological Medical Ultrasound Center

Kyiv, Ukraine

ABSTRACT

Vascular pathologies constitute a significant part of human's diseases and their rate tends to increase. Numerous investigations of brain blood flow in a normal condition and in a pathological one has created a new branch of modern medicine - angioneurology. It combines the information on brain angioarchitecture and on blood supply in a normal condition and in a pathological one. Investigations of a disease's development constitute an important problem of a modern medicine.

Cerebrum blood supply is regulated by arterial inflow and venous outflow, but, unfortunately, in the literature available arterial and venous beds are considered separately. This causes an one-sided interpretation of atherosclerotical and discirculatory encefalopathies. As arterial inflow and venous outflow are interrelated, it seems to be expedient to perform a complex estimation of arteriovenous interactions, prove a correlation dependence connection between the beds and find a dependence in a form of mathematical function. The results will be observed clearly in the graphs.

There were 139 patients aged from 2 up to 70 examined in the "Istyna" Scientific Medical Ultrasound Center by means of a Logidop 2 apparatus manufactured by Kranzbü hler, Germany using a technique of cerebral arteries and veins ultrasound location (invented and patented by Ulyana Lushchyk, State Patent of Ukraine N10262 of 19/07/1995). A clinical interpretation of the results obtained was performed.

With the help of this technique and ultrasound Dopplerography the blood flow in major head and cervical arteries was investigated. While performing a visual graphic analysis we paid attention to the changes of carotid artery (CA), internal jugular vein (IJV) and supratroclear artery's (STA) hemodynamical parameters. Generally accepted blood flow parameters: FS - maximal systolic frequency and FD -

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Current Controlled Trials in Cardiovascular Medicine	Vol. 1(1); 2000
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BMJ 2001; 323: 1151–1155 (17 November)

Interferon alfa with or without ribavirin for chronic hepatitis C: systematic review of randomised trials

Lise L Kjaergard, *research fellow*[a], Kim Krogsgaard, *research director*[b], and Christian Gluud, *chief physician*[a]

[a]Cochrane Hepato-Biliary Group, Copenhagen Trial Unit, Centre for Clinical Intervention Research, H:S Rigshospitalet, DK-2100, Copenhagen, Denmark, [b]Clinical Research Unit, H:S Hvidovre Hospital, DK-2650, Hvidovre, Denmark

Correspondence to: L L Kjaergard kjaergard@ctu.rh.dk

Accepted: 23 July 2001

Editorial by Davis

Abstract

Objective: To assess the efficacy and safety of interferon alfa with or without ribavirin for treatment of chronic hepatitis C.

Design: Systematic review of randomised trials on interferon alfa plus ribavirin combination therapy versus interferon alfa. Patients were naive (not previously treated with interferon), relapsers (transient response to previous interferon therapy), or non-responders (no response to previous interferon therapy).

Studies reviewed: Of 1155 references identified, 48 trials with 6585 patients met the inclusion criteria. Patients were followed to the end of treatment in 20 trials and in 28 trials for 12-96 weeks after treatment.

Main outcome measures: Virological response and morbidity plus mortality

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Anthrax in the New Millennium

Diagnosing and treating a potential killer. (Copyright Current Science Inc.)

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THE LANCET Infectious Diseases
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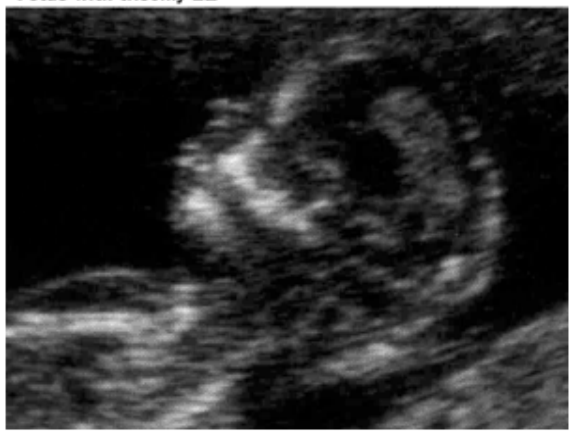
Prenatal diagnosis of Down's syndrome

Fetus with trisomy 21



Use of invasive tests such as amniocentesis or chorionic villus sampling for prenatal diagnosis of Down's syndrome (to look for trisomy 21--a chromosome abnormality) carries a 1% risk of miscarriage. New research shows that looking at the fetal profile during ultrasound examination may provide a safer alternative--by checking for the presence of the nasal bone. In a UK study published in *The Lancet* this week, Simona Cicero and colleagues report that the nasal bone was visible in 99.5% of chromosomally normal fetuses. If the mother's age and nuchal translucency (a measurement of part of the baby's neck) are also taken into account, the sensitivity of the method would increase and the false-positive rate would decrease, they say. But they caution that

A selection from thelancet.com . . .

Global peer-review initiative. *The Lancet* is inviting comments on a meta-analysis of IIb/IIIa inhibitor therapy in acute coronary syndromes (click here for pdf file, 200K), and send comments by e-mail to correspondence@lancet.com.

Criminal deterrence as a medical intervention? Targeted policing and increased rates of conviction, together with pre-school education and family support, "should be integrated into strategies for injury prevention", concludes Prof Jonathan Shepherd from the Violence Research Group, UK. Click here to read more.

Painters and the American West. *"Cowboys and Indians on horseback, pursued and pursuing, galloping across vast plains studded with mountains and framed by endless skies: this is the familiar scenario of America's Old West." Read more about this exhibition now showing at the Joslyn Art Museum, Omaha, USA.*

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- Descrivere lo stato dell'arte
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- Pubblicare anche gli studi negativi
- Ridurre i bias di pubblicazione

Esempi di registri di sperimentazioni cliniche

Physician Data Query (PDQ)

- National Cancer Institute
- Sperimentazioni cliniche in ambito oncologico (2.000 ongoing 10.000 concluse)
- Interrogazione per tutti i dati raccolti (trattamento,acronimo,nome dello studio, fase, popolazione studiata,..)
- http://cancernet.nci.nih.gov/pdq.html

CardioSource

- ACC, ESC, Elsevier
- 500 sperimentazioni cliniche in ambito cardiovascolare
- Interrogazione per trattamento,acronimo,nome dello studio, stato pubblicazione
- http://www.cardiosource.com

Stroke Trials Directory

- American Stroke Association, NINDS
- Sperimentazioni cliniche sull'ictus
- Interrogazione per trattamento, acronimo, nome dello studio, tipologia dello studio
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Stroke Trials

Multicentre Acute Stroke Trial-Italy
MAST-I

74

Contact : Prof Livia Candelise, Istituto di Clinica Neurologica, Via F Sforza 35, 20122 Milano, Italy

Status

Results published 12/95.

Intervention(s)

Aspirin (acute stroke)
Antiplatelet agent; inhibits thromboxane A2

Streptokinase (Streptase®)
Thrombolytic agent

Purpose

To determine whether, separately or together, streptokinase and aspirin have clinical benefits in acute ischemic stroke similar to those in acute myocardial infarction.

Design

Study Design: Randomized, controlled, multi-center, open trial of 622 patients.

Inclusion Criteria: Acute ischemic stroke presenting within 6 hours of symptom onset. No clear indication for or contraindication against streptokinase or aspirin.

Exclusion Criteria: Intracerebral hemorrhage, severe coma without any purposeful motor response, rapid resolution of neurological symptoms, and any medical

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Stroke Interventions

Streptokinase 36

Streptase®, Kabikinase®

Phase No clinical development in stroke

Action Thrombolytic agent

Company Streptase®: Hoechst Marion Roussel, distributed by Astra USA; Kabikinase®: Pharmacia & Upjohn AB

Status US FDA approved for: acute evolving transmural myocardial infarction, pulmonary embolism, deep vein thrombosis, arterial thrombosis or embolism, occlusion of arteriovenous cannulae. In stroke clinical trials, intravenous streptokinase increased stroke mortality or morbidity in several studies. No further development in stroke.

Source Published reports.

Trials

Completed
- Australian Streptokinase Trial (ASK)
- Multicenter Acute Stroke Trial-Europe (MAST-E)
- Multicentre Acute Stroke Trial-Italy (MAST-I)

Publications

Web Thrombolytic Agents, Systemic Patient Information (MEDLINEplus)

ClinicalTrials.gov

- National Institutes of Health, National Library of Medicine
- 5.000 sperimentazioni per qualunque area medica, finanziate da NIH
- Interrogazione per area medica, per malattia, per parole chiave, trattamento, fase, tipo di popolazione
- Integrazione con MedlinePlus
- http://www.clinicaltrials.gov

Observational Aspirin Use and CVD in the Physicians' Health Study

This study is completed.

Sponsored by

National Heart, Lung, and Blood Institute (NHLBI)

Purpose

To analyze existing data from the Physicians Health Study (PHS), a randomized primary prevention trial of low-dose aspirin and beta carotene conducted among 22,071 U.S. male physicians, to address questions concerning aspirin and cardiovascular (CV) disease that could not adequately be addressed during the randomized aspirin period.

Condition
Cardiovascular Diseases
Coronary Disease
Heart Diseases
Myocardial Infarction
Cerebrovascular accident

MEDLINE*plus* related topics: Coronary Disease; Heart Attack; Heart Diseases (General); Stroke

Study Type: Epidemiology

Location and Contact Information

Cook, Nancy R. Boston, Massachusetts, United States

Study chairs or principal investigators

Study chairs or principal investigators

Cook, Nancy R., Study Chair
Brigham and Women's Hospital Boston, Massachusetts, United States

More Information

Results

The randomized aspirin component of the Physicians' Health Study (PHS) was terminated early, after 5 years, primarily because of the emergence of a statistically extreme 44 percent reduction of first myocardial infarction (MI) among those assigned to aspirin. As a result, there were insufficient numbers of strokes or cardiovascular disease (CVD)-related deaths to evaluate these end points definitively. The analysis collected data on self-selected aspirin use until the beta carotene component ended as scheduled after 12 years. Posttrial use of aspirin was assessed at the 7-year follow-up among 18 496 participants with no previous reported CVD. Randomized and posttrial observational results in the PHS were compared, and differences between those self-selecting aspirin and those not were examined. At 7 years, 59.5 percent of participants without CVD reported self-selected aspirin use for at least 180 days per year, and 20.8 percent for 0 to 13 days per year. Use was significantly associated with family history of MI, hypertension, elevated cholesterol levels, body mass index, alcohol consumption, exercise, and use of vitamin E supplements. In multivariate analyses, self-selected aspirin use for at least 180 vs 0 to 13 days per year was associated with lower risk for subsequent MI, no relation with stroke, and significant reductions in CVD-related and total mortality.The authors concluded that these associations between self-selected aspirin use and CVD risk factors increase the likelihood of residual confounding and emphasize the need for large-scale randomized trials, such as the ongoing Women's Health Study, to detect reliably the most plausible small to moderate effects of aspirin in the primary prevention of stroke and CVD-related death.

Publications that report on this study

Cook NR, Hebert PR, Manson JE, et al: Self-selected posttrial aspirin use and subsequent cardiovascular disease and mortality in the Physicians' Health Study. Arch Intern Med, 160(7):921-928, 2000.

Study ID Numbers 5010
NLM Identifier NCT00005493
Date study started April 1, 1998; Date Study Completed March 31, 2001
Last Updated September 21, 2000

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I meta-registri

meta-Randomized Clinical Trials (mRCT)

- Current Controlled Trials
- 11.000 sperimentazioni cliniche
- 21 registri internazionali
- Raccolta di un set minimo (comune) di informazioni da ogni registro
- http://controlled-trials.com

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Search the *m*RCT

Enter keywords here: CURE

Display 10 **results** by register

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Search all registers

Registers within the mRCT

- Action Research
- Alzheimer's Society
- British Heart Foundation
- Canadian HIV Trials Network (CTN)
- Cardiosource
- CTSU - trials being randomised by the Clinical Trial Service Unit, Oxford
- GlaxoSmithKline (access restricted to healthcare researchers & professionals only)
- HIV InSite: Trials Search
- Hong Kong Health Services Research Fund
- Laxdale Limited
- Leukaemia Research Fund

Registers on other websites searchable via the *m*RCT

- CaP CURE (Association for the Cure of Cancer of the Prostate) - Temporarily Unavailable
- National Institutes of Health (NIH) - have allowed searches to include access to randomised trial records held within the NIH *ClinicalTrials.gov* website

UPDATE

Support for trial registration/numbering

Relevant articles

Update archive

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Source of record	Cardiosource
Title of trial	**Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico - 3**
Acronym	GISSI-3
Design/methodology	Randomized controlled trial.
Disease	Myocardial infarction (MI)
Purpose of trial	To evaluate the efficacy of a treatment with angiotensin converting enzyme (ACE) inhibitors and/or nitrates on 6-week mortality following acute MI; evaluation of the extent to which such a favourable effect on left ventricular (LV) function (measured at 6 weeks), if present, is maintained up to 6 months following the event: the evaluation is carried out on the combined endpoint of mortality and LV damage
Status	published
Further information	The Cardiosource trial records in the *meta*Register were last updated on 21 February 2001. Click here to link to the Cardiosource site where you can obtain full details of this trial. The registry of randomized cardiovascular clinical trials on Cardiosource provides a unique resource containing more than 600 ongoing and recent trials, as well as a listing of major trials going back many years. The site requires registration; access to the clinical trials database (and several other services) is free.

*meta*Register (*m*RCT)
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ISRCTN

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INTERNATIONAL STANDARD RANDOMISED CONTROLLED TRIAL NUMBER (ISRCTN)

COMING SOON...

The International Standard Randomised Controlled Trial Number (ISRCTN) is a simple numeric system for the unique identification of trials worldwide. It will simplify the identification of trials and provide a unique number that can be used to track all publications and reports resulting from each trial.

Current Controlled Trials has offered to generate and record these numbers so that they are accessible via this website. Please contact us if you would like to receive further information about the ISRCTN scheme.

A brief introduction to the ISRCTN scheme has been prepared in French, German and Spanish, and other languages will be added.

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metaRegister of Controlled Trials

Introduzione a *Current Controlled Trials* e *meta*Register of Controlled Trials

"La registrazione di tutte le sperimentazioni cliniche non può essere più messa in discussione" (BMJ e The Lancet, ottobre 1999).

A cosa può servire il *meta*Register?

- Assistere nella pianificazione di nuovi trial
- Evitare l'inutile duplicazione della ricerca
- Favorire la collaborazione tra ricercatori
- Ottimizzare la distribuzione dei fondi per la ricerca
- Facilitare ai pazienti l'accesso all'informazione e favorire il loro reclutamento per la partecipazione alle sperimentazioni cliniche
- Migliorare le opportunità per la ricerca metodologica
- Ridurre le discrepanze tra protocolli originali dei trial e risultati successivamente pubblicati
- Ridimensionare il bias di pubblicazione

A chi può essere utile il *meta*Register?

Il sito Current Controlled Trials (http://controlled-trials.com) viene realizzato nell'ottobre del 1998 in risposta alla crescente domanda di maggiore trasparenza sulle sperimentazioni cliniche.

Il *meta*Register of Controlled Trials (*m*RCT) aiuta a promuovere la disponibilità e lo scambio

d'informazioni sui trial condotti in tutte le aree assistenziali affinché:

- Ricercatori e soggetti finanziatori evitino di duplicare la ricerca e sprecare ingenti quantità di risorse
- Le revisioni sistematiche e le meta-analisi identifichino eventuali bias di pubblicazione
- Pazienti e medici possano disporre di un'informazione dettagliata ed accurata sui trattamenti, così da informare meglio le proprie decisioni