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Thrombosis Prevention Trial

Submission date 07/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/09/2005	**Overall study status** Completed	
Last Edited 29/05/2007	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Tom Meade

Contact details
Non-communicable Disease Epidemiology Unit
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7927 2182
tom.meade@lshtm.ac.uk

Additional identifiers

Study information

Scientific Title

Acronym
TPT

Study objectives

That primary prevention treatment in men at high risk with low intensity oral anticoagulation with warfarin and/or 75 mg aspirin daily (i.e. factorial design) reduces coronary heart disease events by 30%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial.

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Thrombosis

Interventions
Oral anticoagulation with warfarin to International Normalised Ratio of 1.5 and/or 75 mg aspirin daily compared with double placebo treatment, i.e. four treatment groups:
1. Active warfarin and active aspirin
2. Active warfarin and placebo aspirin
3. Placebo warfarin and active aspirin
4. Placebo warfarin and placebo aspirin

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Warfarin and aspirin

Primary outcome(s)
All coronary heart disease events; fatal and non-fatal coronary events separately.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/09/1997

Eligibility

Key inclusion criteria
In top 20% of risk score distribution based on smoking history, family history, systolic blood pressure, body mass index, blood cholesterol, factor VII activity, plasma fibrinogen. 5499 men aged 45-69 recruited in 108 practices in the Medical Research Council's General Practice Research Framework.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
Already on antithrombotic treatment; high risk of bleeding; liver or renal disease; serious concomitant disease; at discretion of general practitioner

Date of first enrolment
01/09/1988

Date of final enrolment
01/09/1997

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Non-communicable Disease Epidemiology Unit
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Sponsor not defined - Record provided by the Medical Research Council (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	24/01/1998		Yes	No