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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
All coronary heart disease events; fatal and non-fatal coronary events separately.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1988

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

Age group
Adult

Sex
Male

Target number of participants
4500 (5499 actually recruited).

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
England

United Kingdom

Study participating centre
Non-communicable Disease Epidemiology Unit
London
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Sponsor information

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

Sponsor details
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Sponsor type
Not defined

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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