

Thrombosis Prevention Trial

Submission date 07/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/05/2007	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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
United Kingdom
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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