

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

Protocol serial number

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

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