

# Thrombosis Prevention Trial

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## 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

**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?
<a href="#">Results article</a>	Results:	24/01/1998		Yes	No