

# A multicentre Prospective Randomised Controlled Trial of Thrombosis Prophylaxis with Warfarin in Cancer Patients with Central Venous Catheters (CVCs)

<b>Submission date</b> 17/02/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/04/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/how-much-warfarin-prevents-catheter-clots>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00024297

### Protocol serial number

G84/5337

# Study information

## Scientific Title

A multicentre Prospective Randomised Controlled Trial of Thrombosis Prophylaxis with Warfarin in Cancer Patients with Central Venous Catheters (CVCs)

## Acronym

WARP

## Study objectives

Primary:

1. To determine the utility of warfarin in cancer patients with CVCs in reducing thrombosis rates

Secondary:

2. To determine whether different warfarin dosing strategies lead to different thrombosis rates

3. To monitor the trial-related adverse events across the three arms

4. To compare the trial-related costs between the three arms

5. To compare survival of patients in the warfarin and no warfarin arms

## 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)

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

Cancer

## Interventions

Uncertain one indication for warfarin for prophylaxis of thrombosis:

Intervention A - No warfarin

Intervention B - Warfarin 1 mg/day (fixed dose)

Intervention C - Warfarin - individualised dose to maintain International Normalised Ratio (INR) between 1.5 and 2.0

or

Uncertain two indication for warfarin for prophylaxis of thrombosis:

Intervention A - No warfarin

Intervention B - Warfarin 1 mg/day (fixed dose)

Certain indication for warfarin for prophylaxis of thrombosis:

Intervention B - Warfarin 1 mg/day (fixed dose)

Intervention C - Warfarin - individualised dose to maintain INR between 1.5 and 2.0

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

The number of catheter related thrombotic events

### **Key secondary outcome(s)**

1. The number of other thrombotic events
2. The duration of catheter patency
3. The frequency and severity of trial-related adverse events
4. Costs:
  - a. Trial-related outpatient, inpatient and GP attendances
  - b. Diagnostic procedures for confirmation of thrombosis and cost incurred by patients and patient preference for alternative management options (dependent upon primary outcome)
5. Patient survival

### **Completion date**

15/10/2000

## **Eligibility**

### **Key inclusion criteria**

1. Histologically or clinically confirmed diagnosis of cancer
2. Patients who are due to have a CVC inserted for administration of chemotherapy
3. Aged at least 16
4. Adequate haematological, hepatic and renal function
5. Able to provide written informed consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Patients with contraindication to warfarin (including congenital bleeding disorders, anatomic lesions that bleed e.g. duodenal ulcers and profound concomitant therapy interaction)
2. Patients currently on warfarin
3. Patients who have previously been entered into WARP
4. Use of CVC for additional purposes with the exception of antibiotic therapy and blood products
5. Pregnant or lactating women
6. Fertile persons, not taking adequate contraceptive measures

**Date of first enrolment**

01/12/1999

**Date of final enrolment**

15/10/2000

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Cancer Research UK

Birmingham

United Kingdom

B15 2TT

## Sponsor information

**Organisation**

Cancer Research UK (UK)

**ROR**

<https://ror.org/054225q67>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (UK) (ref: C2273/A3823)

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

**Funder Name**

Medical Research Council (MRC) (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	14/02/2009		Yes	No
<a href="#">Plain English results</a>				No	Yes