

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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	results	14/02/2009		Yes	No
Plain English results				No	Yes