ISRCTN50312145 https://doi.org/10.1186/ISRCTN50312145

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

Registration date
07/04/2004

Overall study status
Completed

Last Edited
17/10/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/how-much-warfarin-prevents-catheter-clots

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00024297

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
The number of catheter related thrombotic events

Secondary outcome measures
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

Overall study start date
01/12/1999

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

Age group
Adult

Sex
Both

Target number of participants
1400

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
England

United Kingdom

Study participating centre
Cancer Research UK
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Cancer Research UK (UK)

Sponsor details
Institute for Cancer Studies
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Sponsor type
Charity

Website
http://www.cancerresearchuk.org/

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