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Does low dose oral vitamin K reduce the risk of bleeding, without causing thrombosis, in patients with warfarin-associated coagulopathy: a randomised clinical trial

Submission date
29/06/2004

Registration date
22/07/2004

Last Edited
31/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Haematological Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

ClinicalTrials.gov (NCT)
NCT00143715

Protocol serial number
MCT-66693

Study information

Scientific Title
Does low dose oral vitamin K reduce the risk of bleeding, without causing thrombosis, in patients with warfarin-associated coagulopathy: a randomised clinical trial

Study objectives
The objective of this trial is to determine if oral vitamin K reduces the risk of bleeding in patients with warfarin-associated coagulopathy, without causing thrombosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from McMaster University Research Ethics Board, Hamilton, Ontario (Canada) on the 19th April 2004 (ref: R.P. #04-2327).

Study design
Multicentre, international, two arm, randomised parallel placebo/drug trial with study participant, study investigator, caregiver outcome assessor and data analyst blinded.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coagulopathy due to warfarin therapy

Interventions
Randomised patients (with INR between 4.5 and 10) will receive either low-dose oral vitamin K, or matching placebo, and will be followed for thrombosis and bleeding outcomes.

Patients with INR greater than 10 (a cohort study), will receive a 2.5 mg dose of oral vitamin K and will be monitored for bleeding and thrombosis.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin K

Primary outcome(s)
Proportion of patients with bleeding in each arm.

Key secondary outcome(s))
1. Major haemorrhage, or all clinically overt hemorrhage thrombosis and a composite of these two measures
2. Changes in INR values
3. Cost effectiveness

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. 660 patients of either sex
2. Aged 18 and over
3. With International Normalised Ratio (INR) values of 4.5 to 10.0 and for cohort study: patients with INR values greater than 10

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Active bleeding
2. Geographic inaccessibility and lack of informed consent
3. Age less than 18 years
4. Warfarin is being discontinued
5. Vitamin K allergy

Date of first enrolment
01/09/2004

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Canada

Italy

United States of America

Study participating centre
St Joseph's Hospital
Hamilton, Ontario
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Sponsor information

Organisation
Canadian Institutes of Health Research (CIHR) (Canada)

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-66693)

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	03/03/2009	31/01/2019	Yes	No