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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

Recruitment status
No longer recruiting

Registration date
22/07/2004

Overall study status
Completed

Last Edited
31/01/2019

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

Contact name
Dr Mark Crowther

Contact details
St Joseph's Hospital
Room L 208
50 Charlton Avenue East
Hamilton, Ontario
Canada
L8N 4A6
+1 905 521 6024
crowthrm@mcmaster.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00143715

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Proportion of patients with bleeding in each arm.

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

Overall study start date
01/09/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
660 (724 enrolled in RCT and 107 in parallel cohort study as of 19/10/2007)

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
Canada
L8N 4A6

Sponsor information

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

Sponsor details
Room 97, 160 Elgin Street
Address locator: 4809A
Ottawa, Ontario
Canada
K1A 0W9
+1 888 603 4178
info@cihr-irsc.gc.ca

Sponsor type
Research organisation

Website
http://www.cihr-irsc.gc.ca/

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

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?
Results article	results	03/03/2009	31/01/2019	Yes	No