

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	☒ Prospectively registered
Registration date 22/07/2004	Overall study status Completed	☐ Protocol
Last Edited 31/01/2019	Condition category Haematological Disorders	☐ Statistical analysis plan
		☒ 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).

Primary study design

Interventional

Study design

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

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

Canada

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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