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Venous thromboembolism in care homes

Submission date
05/06/2013

Recruitment status
No longer recruiting

Registration date
26/09/2013

Overall study status
Completed

Last Edited
24/01/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Around 60,000 deaths a year in the UK are due to venous thromboembolism (VTE) (a blood clot in a vein), with around 50% of these acquired in hospital. The clinical benefit of treatment to prevent VTE in hospitals is established while in the care home (CH) setting we have little understanding of VTE incidence, or prevention and treatment strategies. CH residents represent a significant public health problem and have a similar risk of developing VTE as hospital in-patients; however, there are few data currently available on the scale of the problem. This study aims to determine for the first time the incidence of VTE among CH residents in the UK.

Who can participate?
Care home residents, male and female, aged 18 years and above

What does the study involve?
This is an observational study and no treatment is given or withheld from participants. Participants undergo a case note review of their care home notes and GP (doctor) medical notes on enrolment and one year after enrolment. Should a participant develop a VTE whilst taking part in the study any treatment given follows the normal routine as decided by the treating doctor. Participants who die prior to the one-year follow-up have end of study status and have a notes review following their death.

What are the possible benefits and risks of participating?
This study will help us better understand the incidence of VTE, and prevention and treatment options in CH residents.

Where is the study run from?
Care homes in Birmingham and Oxford will be recruited to the study. GP practices that care for recruited care homes will also be recruited to the study. The study is being organised by a team of researchers from the primary care departments of the University of Birmingham and the University of Oxford (UK).

When is the study starting and how long is it expected to run for?
August 2013 to April 2014

Who is funding the study?
The study is funded by the Primary Care Research Trust of Birmingham and Midlands Research Practices Consortium (PCRT), and the NIHR School for Primary Care Research, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14555

Study information

Scientific Title
A prospective cohort observational study to determine the incidence of venous thromboembolism among care home residents

Acronym
VTEC

Study objectives
Around 60,000 deaths a year in the UK are due to venous thromboembolism (VTE) with around 50% of these acquired in hospital. Whilst the clinical benefit of prophylactic treatment for VTE in hospitals is established, in the care home (CH) setting we have little understanding of VTE incidence, or prevention and treatment strategies. CH residents represent a significant public health problem with a similar risk profile to hospital in-patients; however there are few data currently available on the scale of the problem.

This study aims to determine for the first time the incidence of VTE among care home residents in UK. We propose a prospective cohort observational study of consecutive care home residents

to determine incidence rates of VTE, VTE related deaths, non-hospital intervention and admissions to hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Black Country Research Ethics Committee, 06/06/2013, ref: 13/WM/0118

Study design
Prospective cohort observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Disease: All Diseases/Venous Thromboembolism

Interventions
Study participants will undergo two case note reviews comprising of a baseline assessment and a follow up assessment one year after enrolment.

The baseline assessment will include data on levels of VTE risk, demographics, mobility index and VTE prevention strategies.

Year one follow up assessment will comprise the index events: hospital admission, non-hospital intervention, diagnosed VTE.

Participants who die prior to the year one follow up will have end of study status and have a notes review following their death. For all deaths research staff will abstract available clinical data from death certificates, nursing home records and hospital discharge letters held in general practitioner (GP) clinical files in order to ascertain whether the event was possibly VTE related.

Follow up length: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The rate of VTE events per 100 person years measured 12 months from enrolment

Key secondary outcome(s))
1. Associated non-hospital interventions
2. Hospital admissions and deaths

Measured 12 months from enrolment

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Care home resident, male and female, aged 18 and above
2. Able to consent (either self or by consultee)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Currently participating in clinical trials
2. Residents receiving end of life care with life expectancy < 6 months
3. Temporary residents not expected to stay in the care home for the next 12 months

Date of first enrolment
01/08/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Health and Population Sciences
Birmingham

United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research (UK)

Funder Name
Primary Care Research Trust of Birmingham and Midlands Research Practices Consortium (UK)

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	01/02/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes