

Age and Thrombosis: Acquired and Genetic risk factors in the Elderly

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Primary question: What are the risk factors of VT in the older population? Secondary questions: What is the frequency and seriousness of the PTS in the elderly and which impact has the VT on the QOL and the functionality of this group.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Age related factors
Study type	Observational invasive

Summary

ID

NL-OMON32236

Source

ToetsingOnline

Brief title

AT AGE study

Condition

- Age related factors
- Embolism and thrombosis

Synonym

deep venous thrombosis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Leducq International Network Against Thrombosis (LINAT); a Foundation which is dedicated to improving human health through international efforts to combat cardiovascular disease.

Intervention

Keyword: elderly, riskfactors, venous thrombosis

Outcome measures

Primary outcome

The riskfactors of developing VT can be determined. Furthermore specific riskgroups in developing VT in the elderly can be described.

Secondary outcome

The frequence and seriousness of the post-thrombotic syndrome of the elderly will be defined, and the quality of life in the elderly can be compared with the general queality of life in the older population.

Moreover the influence of VT on the functionality of the elderly will be assessed.

Study description

Background summary

The incidence of venous thrombosis (VT) is one of 100 older people per year against an incidence of 1-3 per 1000 per year in the general population. The prevalantce of thrombosis wil increase because an increase of percentage elderly in the world population in the coming decennia. In the last years several genetic and environmental riskfactors are described for developing VT, although until this moment little is known about the specific riskfactors of VT in the elderly. Futhermore scarce is known about the development of PTS in this population and the impact of the event on people's quality of life and mobility.

Study objective

Primary question: What are the riskfacors of VT in the older population?

Secondary questions: What is the frequence and seriousness of the PTS in the elderly and which impact has the VT on the QOL and the functionality of this

group.

Study design

Case-control study in which patients recruitment will be done via the anti-coagulation clinics in Leiden and Haarlem and the controls will be approached via the LEON, a network of general practitioners.

Two patient-visits will be planned, 1 month and 1 year after the diagnosis to fill in questionnaires and to obtain a bloodsample. The controls will be invited for one visit to fill in the questionnaire and for one bloodsample.

Study burden and risks

Patients: two visits of 1 hour, an interview, two times bloodsamples in one year. Bloodpressure measurement, length and weight measurement.

Controls: one visit of 1 hour, an interview, two times bloodsamples in one year. Bloodpressure measurement, length and weight measurement.

Collection of small blood samples is a standard procedure in medical practice. Therefore, the risk of study participation is expected to be low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

venous thrombotic event (lower extremities and pulmonary embolus)

age 70 and older

Exclusion criteria

active malignancy (palliative phase or cancer-treatment for the last 6 months)

serious cognitive disorder

non-dutch speaker

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 16-06-2008

Enrollment: 500

Type:

Actual

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

CCMO

ID

NL21966.058.08