

Thrombogenesis in antipsychotics

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Is there an increase in markers of thrombogenesis (platelet activation, d-dimer, von willebrandfactor, OPG) in elderly users of antipsychotics six to ten days after the start in comparison to the same markers before start of the antipsychotic...

Ethical review

Approved WMO

Status

Recruitment stopped

Health condition type

Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Study type

Observational invasive

Summary

ID

NL-OMON37658

Source

ToetsingOnline

Brief title

Thrombogenesis in antipsychotics

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Central nervous system vascular disorders
- Psychiatric and behavioural symptoms NEC

Synonym

use of antipsychotics, use of neuroleptics

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW (financiering via Ephor;expertisecentrum farmacotherapie bij ouderen)

Intervention

Keyword: Antipsychotic agents, Biological markers/blood, Elderly, Thrombogenesis

Outcome measures

Primary outcome

1. Platelet activation tests
2. D-dimeer
3. Von Willebrand Factor
4. Osteoprotegerine (OPG)

Secondary outcome

Age (in years)

Sexe (male/female)

Comorbidity

In case of dementia, also the seriousness of the dementia according to the

Clinical Dementia Rating scale

In case of Parkinson(ism), also the seriousness according to the Hoehn en Yahr

criteria

Medication

Type antipsychotic

Dosage of the antipsychotic

Indication of prescribing the antipsychotic medication

The medical record will be used as the source for the secondary study

parameters

Study description

Background summary

The food and drug administration notified in 2005 that antipsychotics are associated with an increased risk of mortality in elderly patients. This fact can not be explained by more coronary events, but there seem to be more cerebrovascular events and thrombo-embolic events. A possible explanation is an increase in thrombogenesis factors in blood. In elderly users of antipsychotics there is no answer to the question what the mechanism is behind the increased (cerebro) vascular mortality.

Study objective

Is there an increase in markers of trombogenese (platelet activation, d-dimeer, von willebrandfactor, OPG) in elderly users of antipsychotics six to ten days after the start in comparison to the same markers before start of the antipsychotic medication?

Study design

Prospective study

Study burden and risks

Two times vena puncture

The burden for the patient is low, there are no risks for the participants

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

Age above 65 years

start of an antipsychotic drug

informed consent

Exclusion criteria

history of venous tromboembolism or deep venous thrombosis

malignancy with treatment in the last 6 months or palliative treatment

bedridden or immobilisation for more than three days

operation in the four previous weeks

delirium or acute psychosis, as indication of use of antipsychotic drug

use of an antipsychotic in the 6 months previous to the start of the study

other changes in medication within the 10 days of observation

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 24-01-2013
Enrollment: 20
Type: Actual

Ethics review

Approved WMO
Date: 14-02-2012
Application type: First submission
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO
Date: 05-09-2012
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	ID
CCMO	NL38164.041.11