The Need for Titration or Monitoring of Direct Oral Anticoagulant Treatment: The MONDOAC and KIDOAC study

Published: 18-01-2018
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To determine the within and between variability of pharmacokinetic (PK) profiles in patients treated with DOACs in daily practice

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational invasive

Summary

ID

NL-OMON44541

Source
ToetsingOnline

Brief title
MONDOAC AND KIDOAC

Condition

- Cardiac arrhythmias
- Embolism and thrombosis

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial fibrillation, Direct oral anticoagulant treatment, Pharmacokinetics, Venous thrombosis

Outcome measures

Primary outcome

Blood will be sampled for the measurement of PT and aPTT, Hemoclot (to determine dabigatran concentrations) and anti-Xa levels (to determine rivaroxaban and apixaban concentrations).

Secondary outcome

Not applicable

Study description

Background summary

Since its initial discovery in the early 1940s, vitamin K antagonists (VKAs) have been the cornerstone of anticoagulant treatment. At first developed as a rodenticide, it became immediately clear that VKAs need to be monitored and titrated. Direct oral anticoagulant drugs (DOACs) have recently been developed and marketed to be used in fixed dose regimens without the need for dose titration or monitoring of blood levels. This is considered to be a substantial advantage over VKAs. However, it is doubtful as to whether pharmacokinetic profiles of DOACs are as stable as claimed, that *one size fits all* and that they do not cause serious clinical events when not correctly used. This is certainly true for demanding drugs like DOACs, the efficacy of which will be affected by even one delayed or missed dose. Recently we and others observed that after starting DOAC for in principal lifelong medication, nearly half of patients stopped taking their DOAC within 2 years. Why this persistence to DOAC treatment is so low is currently unknown.

Study objective

To determine the within and between variability of pharmacokinetic (PK) profiles in patients treated with DOACs in daily practice

Study design

single arm, open label, multicenter clinical trial

Study burden and risks

In total 60 ml of blood will be collected through veni punction. Veni punction can be painful en cause a bruise or bleeding at the site of insertion of the needle

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

Patients with (initial or recurrent) confirmed symptomatic deep vein thrombosis, pulmonary embolism or atrial fibrillation who are allowed to switch (or switched <=5 days) vitamin K antagonist treatment to DOAC by their treating physician

Exclusion criteria

1. Life expectancy less than 6 months
2. Serious or unstable medical or psychological conditions that, in the opinion of the investigator, would compromise the person*s successful participation in the study as required by protocol (including alcohol or drug abuse)
3. Previous participation in the study

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2018
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Eliquis
Generic name:	Apixaban
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Pradaxa
Generic name:	Dabigatran
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xarelto
Generic name:	Rivaroxaban
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-01-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-02-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-05-2018
Application type:	Amendment
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	ID
EudraCT	EUCTR2017-003677-33-NL
CCMO	NL63306.058.17