What is the effect of packaging vitamin-K antagonists via Multidose Drug Dispensing compared to regular dispensing on the time in therapeutic range of patients under the supervision of the anticoagulation Clinic Leiden?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27323

Source
Nationaal Trial Register

Health condition

Vitamin K-antagonist (VKA), Time in Therapeutic Range (TTR), Multidose Drug Dispensing (MDD), adherence

Sponsors and support

Primary sponsor: SIR Institute for Pharmacy Practice and Policy
Source(s) of monetary or material Support: 1. Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP)
2. Het platform GDS

Intervention

Outcome measures

Primary outcome

delta TTR between the intervention and control group.

The delta TTR is the absolute difference in TTR six months before the study, and during the study period.

Secondary outcome

1. average number of vitamin K doses for uncontrolled INR

2. average number of control visits at Anticoagulation Clinic

3. average daily dose in the six months before the study and during the study period

4. intra-individual TTR

5. difference in MARS score

6. time above therapeutic range

7. time under therapeutic range

8. proportion of patients with thromboembolic events

9. proportion of patients with serious bleeding.

Study description

Background summary

The effect of the Multidose Drug Dispensing (MDD) on health outcomes is unknown. Although the effect of MDD is unknown, MDD is frequently used in the Netherlands to support mostly the elderly with their medication. MDD can be used to improve patients adherence or support the patient with complex medications regimes. In this study the effect of MDD is investigated in patients using vitamin K-antagonists (VKA). Patients with VKA's are under the supervision of anticoagulation clinics in the Netherlands. Despite the strict supervision of anticoagulation clinics not all patients achieve a stable control of their INR expressed in the Time in Therapeutic Range (TTR). One possible explanation for the unstable control is reduced adherence to the complex dosing regimen of VKA’s. In this study the effect of MDD on the

TTR of patients with a TTR < 65 % will be investigated.
Patients under the supervision of the Anticogulation Clinic Leiden with a TTR < 65% during the past six months will be invited to participate in the study. After informed consent patients are randomised to the intervention or control group. In the intervention group patient will receive the medication via MDD including the VKA. Patients in the control group will receive the vitamin K-antagonist as they are used to, via regular dispensing. After six months the TTR over the study period is determined and compared between the two groups. It’s estimated that patients receiving medication via MDD have an improved TTR compared to the control group.

The study starts at 01-6-2016 and 19 community pharmacies in the catchment area of the Anticoagulation Clinic Leiden participate in the study. The study is a collaboration between the SIR Institute for Pharmacy Practice and Policy, Utrecht University and the Anticoagulation Clinic Leiden.

Study objective

Patients using vitamin K-antagonists are under intensive supervision of anticoagulation clinics in the Netherlands. Despite the supervision, not all patients achieve a time in therapeutic range above 65%. A proposed reason is a reduced adherence to the complex medication regime of VKA. Multidose Drug Dispensing can support the patient with their medication regime. What the effect on TTR is of Multidose Drug Dispensing is unknown. What is the effect packaging vitamin-K antagonists via Multidose Drug Dispensing compared to regular dispensing on the time in therapeutic range?

Study design

Inclusion t=0

- TTR over the past six months using the method described by Rosendaal.

- BMQ, MARS, GFI, Mini-Cog, Questionnaire possible adherence problems

After six months t=1 (end of study)

- TTR over the past six months

- MARS

- average number of vitamin K doses

- average number of control visits at Anticoagulation Clinic

- proportion of patients with thromboembolic events

- proportion of patients with serious bleeding

Intervention

Patients with a low TTR (<65%) will be randomised to the intervention or control group. The intervention group will receive the medication, including the vitamin K-antagonist, via Multidose Drug Dispensing. The control group will receive the vitamin K-antagonist as the patient is used to (via regular dispensing).

Contacts

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Eligibility criteria

Inclusion criteria

TTR < 65% during last 6 months

> 64 years of age

> 4 chronic oral drugs

Lifelong indication for VKA

Vitamin-K antagonist use > 9 months

Patient or partner is responsible for medication

Informed consent

Exclusion criteria

Patients with self-management of VKA medication

Patients with recurrent chemotherapy

Patient with palliative pain medication

Patients who receive home-care responsible for the administration of medication

Patients with VKA distributed via MDD

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2016
Enrollment:	208
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-05-2016
Application type:	First submission

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
NTR-new	NL5738
NTR-old	NTR5883
Other	CME LUMC, UPPER UU : P15.365, UPF1602

Study results