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?

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27323

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: SIR Institute for Pharmacy Practice and Policy
Overige ondersteuning: 1. Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP)
2. Het platform GDS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2016
Aantal proefpersonen:	208
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-05-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5738
NTR-old	NTR5883
Ander register	CME LUMC, UPPER UU : P15.365, UPF1602

Resultaten