Early clozapine discontinuation: who is at risk?

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Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON20555

Bron
Nationaal Trial Register

Aandoening

Psychotic disorders, Schizophrenia, Schizoaffective disorders

Psychotische stoornissen,Schizofrenie, Schizoaffectieve stoornissen

Ondersteuning

Primaire sponsor: Division of Pharmacoepidemiology & Clinical Pharmacology of the Department of Pharmaceutical Sciences
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Discontinuation of clozapine use within one year after the start is the main outcome measure.

Toelichting onderzoek

Achtergrond van het onderzoek

Clozapine is almost always the drug of last resort, so when clozapine is initiated no alternatives with proven efficacy remain. However the discontinuation rate of clozapine treatment is disturbingly high, ranging between 18 and 57%. Discontinuation can be a result of serious adverse events, aversion of the necessary, frequent blood tests or a lack of effect. Considering the high frequency of clozapine discontinuation and the numerous reasons for drug cessation, knowing which patients are at risk for discontinuing clozapine, has important implications. It could help the physician to select patients, eligible for clozapine treatment, who need extra care to prevent early, unwarranted discontinuation. Therefore we aim to develop a multivariate predictive model for clozapine discontinuation after twelve months of therapy in a large, both in and outpatient with psychotic disorders in the Netherlands.

Doel van het onderzoek

Several reasons for clozapine discontinuation are known, but the current evidence identifying patients who are at risk of discontinuation of clozapine is small and not always consistent. Also cultural differences may question if international results are generalizable to other countries worldwide. The available evidence of prediction of clozapine discontinuation is based on relatively small, mainly inpatient populations with follow-up periods ranging from 19 months until 15 years, conducted in the United States and Israel. Therefore, the need for a multivariate predictive model for early discontinuation of clozapine in a large, both in and outpatient population in the Netherlands, still remains.
We aim to develop a multivariate predictive model for clozapine discontinuation after twelve months of therapy in a patient population with psychotic disorders.

Onderzoeksopzet

6 months and 12 months after start of clozapine

Onderzoeksproduct en/of interventie

not applicable (predictive modelling study)

Contactpersonen

Publiek

Marieke Beex-Oosterhuis
Utrecht

The Netherlands
0031-78-6523103

Wetenschappelijk

Marieke Beex-Oosterhuis
Utrecht
The Netherlands
0031-78-6523103

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients, aged 18 years or older, of whom demographical, medical and social data are registered in the AHD and the PCR-MN, between 2001 and 2014, who have been prescribed clozapine are eligible for the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-the absence of any drug-dispensing records over the past two years before introduction of clozapine.

-the absence of drug-dispensing data of any drug in the 12 weeks after cessation of clozapine, if applicable,

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Anders

(Verwachte) startdatum:	15-10-2015
Aantal proefpersonen:	0
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5330
NTR-old	NTR5439
Ander register	Achmea Health Database Onderzoekscommissie : AHDOC-167-001

Resultaten

Samenvatting resultaten

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