Onderzoek naar het DNA medicatie paspoort bij het starten van antidepressiva in de eerste lijn.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	Depressiestoornissen en -afwijkingen
Onderzoekstype	Observationeel onderzoek, met invasieve metingen

Samenvatting

ID

NL-OMON27432

Bron
Nationaal Trial Register

Verkorte titel
PGx-DEP

Aandoening

- Depressiestoornissen en -afwijkingen

Aandoening

mild to moderate depression and anxiety disorders

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor:	Erasmus University Medical Center, Dept. Clinical Chemistry Dr. Molewaterplein 40, 3015 GD Rotterdam
Secundaire sponsoren:	Humo voor huisartsen, Wethouder van Eschstraat 50, 5342 AT Oss, BrabantFarmac ApothekersZorggroep, Mr.

	Goselingstraat 8 5481 BX Schijndel.
Overige ondersteuning:	CZ Wilhelminastraat 39 6131 KM Sittard

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to investigate if PGx-guided treatment with antidepressants (N06A drugs) for mild to moderate depression and/or anxiety disorders is improving therapy (less stops due to inefficacy or side effects) within the first 3 months after start treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Anxiety disorders as a group are the most common mental health problems, occurring in 1/5 of the Dutch population. Whereas, depression is the most frequently occurring isolated psychiatric disorder, with an incidence of 135.600 newly diagnosed individuals per year in the Netherlands [www.trimbos.nl]. The pharmacological treatment of these psychiatric disorders is characterized by low efficacy and high incidence of side effects, both resulting in the need to switch from type of antidepressant in 30% of the patients [The Swedish Council]. Ineffectiveness and adverse drug reactions are partially caused by interindividual variation in drug metabolism. Pharmacogenetic (PGx) analysis can predict this variability in drug metabolism by analysing DNA of a patient. The Royal Dutch Pharmacogenetics Working Group (KNMP) has established evidence-based genotype-guided dosing advices for over 90 drugs, which are currently available in every pharmacy in the Netherlands and clinically used. This PGx diagnostic analysis can be used before start of antidepressant therapy, to maximally benefit from the genetic information in getting patients as quickly as possible on the right medication/dosage, and are currently used to adjust dosing of clinical patients. Erasmus MC received 14,000 PGx test requests (2018, prognosis 2019: 22,000), from which 9,000 in 2018 were related to psychiatric drugs. We see a trend in requesting a full DNA passport, making that an increasing number of patients will have DNA information prior to start of drug therapy. However, there is limited information on what the effects are of this knowledge implementation. The primary care setting is a suitable environment to monitor knowledge implementation, being the effects of using PGx information at start of antidepressant therapy. Important factors that will be addressed are evidence for improved treatment in the

pre-emptive setting and cost-effectiveness.

Onderzoeksopzet

Stepped wedge cluster randomized prospective implementation study

Onderzoeksproduct en/of interventie

farmacogenetica bepaling voor aanvang behandeling met antidepressivum

Inschatting van belasting en risico

Written informed consent will be asked from all participants. Collection of buccal swab material will be performed once in all participants at start of treatment, which poses no additional risk. For participants in the intervention group, PGx outcome and advice will be delivered prior to therapy. Material of patients in the control group will be stored at Erasmus MC and genotyped at the end of the study, so that both groups will have their DNA information (ethical aspect) and this retrospective analysis of endpoints in the control group will be possible. Participants in de intervention group will not have more visits compared to the individuals in the control group. Data will be extracted from the medical records of the patients. Information on quality of life will be collected in both allocation groups with the EQ-5d-5L questionnaire, which will performed at baseline (before start N06A drug) and 1 year after start treatment. The questionnaire will require 5 minutes per assessment (10 minutes total per participant).

Contactpersonen

Publiek

Erasmus University Medical Center
M. Matic
Dr. Molewaterplein 40
3015 GD
Rotterdam
Netherlands

0107038775

Wetenschappelijk

Erasmus University Medical Center
M. Matic

Dr. Molewaterplein 40
3015 GD
Rotterdam
Netherlands

0107038775

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

· ≥18 jaar

· eerste voorschrift N06A geneesmiddel (geen N06A geneesmiddel 1 jaar voor start N06A geneesmiddel)

· diagnose milde tot matige depressie of angststoornis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

geen CYP2C19 en CYP2D6 farmacogenetica test voorhanden of aangevraagd voor einde follow-up

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, met invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2023
Aantal proefpersonen:	280
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-04-2023
Soort:	Eerste indiening
Toetsingscommissie:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL8807
Ander register	METC Erasmus MC : MEC-2019-0770

Resultaten