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Laatst bijgewerkt: 18-08-2022

Succes-rate of discontinuation is higher with more gradual tapering of paroxetine or venlafaxine

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

Verkorte titel
TEMPO

Health condition

Major Depressive Disorder

Ondersteuning

Overige ondersteuning:	ZonMW Goed Geneesmiddelen Gebruik
Primaire sponsor:	AmsterdamUMC (location VUMC) & Radboudumc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of patients who are unable to successfully continue to taper the PAR or VLX and stop taking study-medication or take rescue medication

Secundaire uitkomstmaten

- Withdrawal symptom severity over time (DESS-score)
- Depressive symptoms over time (IDS-SR)
- Relapse/recurrence rate (MDD diagnosis on MINI interview) and time to event during follow-up
- Daily functioning and Quality of life (EQ-5D-5L)
- Attitudes towards and perceived difficulty of discontinuation (patient reported)
- Cost-effectiveness and productivity losses (TiC-P)

- Before and after discontinuation choice and decision times on a task requiring participants to choose how much effort to exert for various amounts of reward

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: For discontinuation, two fundamentally different ways of antidepressant discontinuation exist: 1) a conventional 2-step reduction, halving dosages with available dosage-units and then stop over 2-4 weeks (currently treatment as usual), and 2) more gradual reduction (dose reduction with progressively smaller dosage-units). The crucial difference between these ways of antidepressant discontinuation are free-fall vs. linear decreases of SERT occu¬pancies, respectively. These two ways have not been directly compared in a double-blind RCT. This lack of evidence leaves patients, clinicians, pharmacists and policy-makers uncertain about rational methods to discontinue antidepressants.
Objective: TEMPO will compare two tapering strategies in patients with remitted MDD who use either paroxetine (PAR) or venlafaxine (VLX). We will evaluate effectiveness (number of patients that can discontinue their antidepressant; depression-scores and discontinuation symptoms), pharmacokinetics during the course of discontinuation, relapse rates during 6 months of follow-up after deblinding, patients attitudes and perceived difficulty during discontinuation and cost-effectveness.
Study design: Multicenter randomized (1:1) clinical trial of 200 patients with remitted major depressive disorder (MDD, retrospectively assessed by semi-structured interview) using paroxetine (PAR, 20-50mg, n=100) or venlafaxine (VLX, 75-375mg, n=100). After double blind discontinuation of antidepressants, we will follow patients up for ≥6 months (no medication or blindng).
Study population: Patients (18-75 years) with stable 6-month remission of MDD with confirmed >6 months use of PAR (20-50mg, N=100) or VLX (75-375mg, N=100). Exclusion criteria are psychotic/bipolar disorder, severe drug/alcohol addiction, insufficient mastery of Dutch language.
Intervention: Concealed randomization by computer (1:1) to either of the two tapering strategies.
Main study parameters/endpoints: Rate of failure to successfully discontinue antidepressant: defined as significant deviation from discontinuation antidepressant protocol (e.g. switching to rescue medication, stopping with discontinuation medication) or significant withdrawal symptoms during the double blind phase.

Doel van het onderzoek

Succes-rate of discontinuation is higher with more gradual tapering of paroxetine or venlafaxine

Onderzoeksopzet

Baseline, Randomization (T0), Week 14, Week 52

Onderzoeksproduct en/of interventie

We compare two active tapering strategies

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Age 18-75 years
• Stable 6-month remission of MDD
• Confirmed >6 months use of paroxetine (PAR) or venlafaxine (VLX)
• Previous MDD episode and current remission confirmed with semi-structured psychiatric interview (MINI).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Psychotic/bipolar disorder
• Severe drug/alcohol addiction

• Insufficient mastery of Dutch language.

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Toewijzing :	Gerandomiseerd
Blindering :	Dubbelblind
Controle :	Geneesmiddel

Deelname

Nederland

Status :	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2022
Aantal proefpersonen:	200
Type:	Gerealiseerd

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
na

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

In overige registers

Register	ID
NTR-new	NL9867
Ander register	ZonMW : 10140021910006

Resultaten

Einddatum onderzoek: 31-12-2026

Samenvatting resultaten
tba

Historische versies