Safety of Anthroposophic Medicinal Products

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The reporting rate of adverse drug reactions upon use of anthroposophic medicinal products, as well as the reporting rate of serious adverse drug reactions, is low as retrieved from pharmacovigilance databases of German manufacturers.

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

Samenvatting

ID

NL-OMON27242

Bron
Nationaal Trial Register

Aandoening

safety, adverse events, anthroposophical medicinal products, pharmacovigilance

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The frequency of reported ADRs relative to the total sales volume of AMPs.

Toelichting onderzoek

Achtergrond van het onderzoek

Pharmacovigilance is the pharmacological science of the surveillance of drug safety. Manufacturers of medicinal products, including AMPs, are obliged to collect, detect, monitor and assess the side-effects that occur with their medicinal products through their pharmacovigilance database. Safety data collected and analysed include the number of reported Adverse Drugs Reactions (ADRs) that may occur when AMPs are used by patients. The aim of the study is to investigate the safety status of AMPs through a systematic evaluation of reported ADRs from 2010¨C2017 as identified in the pharmacovigilance databases of German AMP manufacturers. The results of the systematic evaluation will be published in peer-reviewed scientific journals.

Doel van het onderzoek

The reporting rate of adverse drug reactions upon use of anthroposophic medicinal products, as well as the reporting rate of serious adverse drug reactions, is low as retrieved from

pharmacovigilance databases of German manufacturers.

Onderzoeksopzet

ADRs from electronic pharmacovigilance database of AMP manufacturers in Germany as reported to and evaluated by the company in the last eight years (2010¨C2017).

Onderzoeksproduct en/of interventie

Anthroposophic medicinal products

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Only those Adverse Drug Reactions (ADRs) that are reported in humans

- All valid and suspected ADR reports (including those related to off-label use) filed in the period from 1 January 2010 to 31 December 2017, independent from the ADR reporting duty to the European Medicines Agency

- Non-serious and serious ADRs

- ADRs from Anthroposophic Medicinal Products (AMPs) sold in Germany

- ADRs from post-marketing surveillance and clinical/safety trials

- ADRs that are assessed by the responsible person within the company (causal relationship with respect to drug administration is described)

- Spontaneous reports by consumers/patients, health professionals

- Literature cases

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- ADRs from AMPs sold in countries other than Germany

- ADRs for which the causality is assessed by the company as excluded or unlikely/remote

- ADRs from medicinal products with active ingredients which are not prepared according to the Anthroposophic Pharmaceutica Codex (APC)

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-09-2018
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	NL6759
NTR-old	NTR7628
Ander register	METC Brabant : NW2018-57

Resultaten