Safety of Anthroposophic Medicinal Products

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON27242

Source
Nationaal Trial Register

Health condition

safety, adverse events, anthroposophical medicinal products, pharmacovigilance

Sponsors and support

Primary sponsor: Institute for Applied Epistemology and Medical Methodology (IFAEMM)
Zechenweg 6
D-79111 Freiburg, Germany
Tel:+49 761 1560305
Fax: +49 (0)761-1560306
email: anja.glockmann@ifaemm.de

and

Louis Bolk Institute
Kosterijland 3-5
3981 AJ Bunnik
info@louisbolk.nl
tel. +31(0)343 523.860

fax +31(0)343 515.611

Source(s) of monetary or material Support: ESCAMP (European Scientific Cooperative on Anthroposophic Medicinal Products) E04.

European Scientific Cooperative on Anthroposophic Medicinal Products e.V.
Zechenweg 6
D-79111 Freiburg, Germany
Tel. +49 761 1560305
Fax +49 761 1560306
email: info@escamp.org

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The relative frequency of ADRs to subgroups of AMPs, properties of ADRs such as the seriousness, classification according to system organ class (MedDRA), labelling, outcome, type of report, type of reporter and causality as well as characteristics of ADRs to AMP such as the origin of starting materials, dilution of active ingredients (non-diluted versus D1-D3 versus ¡Ý D4 versus composition of dilutions), route of administration (parenteral versus local, versus oral) and indications.

Study description

Background summary

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.

Study objective

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.

Study design

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).

Intervention

Anthroposophic medicinal products

Contacts

Public
Erik Baars
Leiden
The Netherlands
0031 71 5188715
Scientific
Erik Baars
Leiden
The Netherlands
0031 71 5188715

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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)

Study design

Design

Intervention model: Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	0
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6759
NTR-old	NTR7628
Other	METC Brabant : NW2018-57

Study results