1. Abstract

Title

Drug utilization study of dexamfetamine in European countries - Data collection on abuse, misuse, overdose, diversion and dependence related to dexamfetamine in 5 European countries;

Final Report - Version 2.0 - 28 May 2021 / Literature Search

Keywords

abuse, misuse, overdose, diversion and dependence

Rationale and background

Research question and objectives

The research question was to evaluate the emergence or increase of reports on abuse, misuse, overdose, diversion and dependence after launch of dexamfetamine products.

Study design

The data collection was performed by active examination of different kind of information sources like poison control centres/drug monitoring centres and supplemented by searches in the literature and the internet.

Setting

The review of information regarding abuse, misuse, overdose, diversion and dependence was performed across all settings in the target countries.

Variables and data sources

All available indicators like life-time prevalence, 1-year prevalence, risk ratios or cases regarding the untoward use or any qualitative assessment were planned to be extracted.

For information and reports on abuse, misuse, overdose, diversion and dependence related to dexamfetamine use the following data sources were considered: poison control centres/drug monitoring centres; literature databases Medline and Embase; grey literature; and other relevant data sources;

Results

Overall, the search strategies revealed one substantial report on the non-medical use of prescribed amphetamines with regard to the study objectives. According to a representative study in Germany published in 2018, the lifetime prevalence of using prescription drugs containing amphetamines to improve cognitive performance or mood without a medical indication was 1.7%, 0.8% during last year and 0.3% during last month. The exact product

names that fell into the category "prescription drugs containing amphetamines" as well as the exact proportion of dexamfetamine in the total number remained unclear. Two abstracts based on the survey of Non-Medical Use of Prescription Drugs (NMURx) reported -more broadly-information on the non-medical use of prescribed stimulants, including methylphenidate. The last 12-month prevalence of non-medical use of prescribed stimulants was equal or below 1% and the estimated rates were below 1,000 per 100,000 population in all countries (France, Germany, Italy, Spain, and the UK). All studies mentioned that the non-medical use of prescribed stimulants was low compared to other drugs studied. One publication on use of stimulants for neuroenhancement by students in Germany did not detect amfetamine dependence and only scarce diagnoses of amfetamine misuse (1). It remained unclear if the missing information is due to efficient self-control or if participants do not use any stimulants for neuroenhancement.

Over all study periods, only few individual case safety reports related to dexamfetamine were identified in the spontaneous reporting databases (VigiBase, EudraVigilance) and PSURs.

Poison control centres and drug monitoring centres contacted in Denmark, Germany and UK did not report any abuse, misuse, overdose, diversion and dependence related to dexamfetamine. In 2016 and 2017, the TRIMBOS institute in the Netherlands has provided information about a warning regarding fraudulent dexamfetamine prescriptions given in 2015, 2016 and 2017. In 2019, the TRIMBOS Institute referred to an investigative reportage of which they had gained knowledge, in which a reporter was given access to diverted medical dexamfetamine in the student environment. However, this report is not part of a scientific study, so there is a lack of information that would allow further evaluation of this report. In 2020, no relevant information with respect to the study objectives was provided by TRIMBOS.

Discussion

None of the searches revealed any substantial reports on abuse, misuse, overdose, diversion and dependence with a clear reference to the non-medical use of dexamfetamine. The broad search strategy aimed to also detect less prominent reports on non-medical use of dexamfetamine. These findings were supported by responses from poison control centres and drug monitoring centres contacted in Denmark, Germany, Netherlands, Norway and UK. Over the years, however, there has been increasing evidence of misuse and diversion of medical stimulants and more specifically amfetamine-containing stimulants at a low level, although the exact extent of the contribution of dexamfetamine to this has remained unclear in all cases. This search was carried out over 5 years from 2016 to 2020. Based on search findings until September 2020, no evidence of potential abuse, misuse, overdose, diversion or dependence of dexamfetamine on a larger scale was found in the countries studied.

Marketing Authorisation Holder(s)

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