

Adverse drug reactions in children following use of asthma medications

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Asthma is one of the most common chronic diseases in children.

The Faculty of Health and Medical Sciences) In a new study based on EU adverse drug reaction reports, researchers at the University of Copenhagen and the University of Southern Denmark now document that children's use of asthma medications may result in serious adverse drug reactions. The risk of adverse drug reactions is not fully documented in the pre-marketing clinical trials. The new study has been published in the *International Journal of Clinical Pharmacy*.

Since 2007, the European Medicines Agency (EMA), an EU agency, has gathered information on patients' experiences with adverse [drug reactions](#) (ADRs) in the European ADR database, EudraVigilance. Both authorities and pharmaceutical companies have a duty to report

information about ADRs to the database, which provides new knowledge about unknown and serious ADRs:

"We have studied all EU [adverse drug reaction](#) reports on [asthma medications](#) approved for – and used by – [children](#) over a five-year period (2007 to 2011). In the light of the total use of asthma medications, the number of reported ADRs were not overwhelming – a total of 774 ADR reports – however, 85% of these ADRs, almost all reported by physicians, are classified as serious," says Professor Ebba Holme Hansen from the Department of Pharmacy, University of Copenhagen. Together with Professor Lise Aagaard from the University of Southern Denmark, she carried out the new scientific study published in the *International Journal of Clinical Pharmacy*.

The ADR database shows a far higher share of serious ADRs than do the published studies of clinical trials in which the drugs have been tested in children and young people:

"It is an interesting observation and one which health professionals should take into account when prescribing medicine to children," says Ebba Holme Hansen.

Drugs tested in adult men

Drugs in clinical trials are generally tested in young male patients, which the researchers see as a general problem when it comes to adverse reactions in children:

"No one knows the consequences of prescribing drugs to children, who constitute a vulnerable patient group, as knowledge of ADRs in this population is very scarce. Infants under one year of age are prescribed asthma medications as cough medicine, as no alternative treatments are available for very young children. However, our study suggests that

asthma medications are associated with more – and more serious – ADRs than documented by the clinical trials. Especially in the case of children," says Lise Aagaard.

Professor Ebba Holme Hansen adds:

"The published clinical studies on the treatment of children with asthma medications contain very limited data about ADRs, and the most frequently observed ADRs are shortness of breath and coughing. There are not many publicly available articles, and the ADRs mentioned in clinical studies are categorised as non-serious. From the literature, we have, however, learned that several test subjects drop out of the [clinical trials](#) due to serious ADRs – in itself a thought-provoking fact."

Correct use an important parameter

In addition to classic ADRs such as shortness of breath and coughing, the EU ADR reports also include psychiatric ADRs in the form of nightmares and aggression as well as skin rash. Some of the reports also suggest that patients have problems using the asthma medications, including correct inhalation technique:

"In a clinical trial, patients are provided with the assistance and guidance needed to take their medication correctly and at the right time. It is, of course, a totally different situation for sufferers who do not have immediate access to a health professional in their everyday lives. In Denmark, asthma patients can have their inhalation technique checked at pharmacies via a 'Check your inhalation' service provided free of charge by the Danish state," says Lise Aagaard.

More information: www.ncbi.nlm.nih.gov/pubmed/25288145

Provided by University of Copenhagen

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