

Chronic exposure to phthalate containing drugs and the risk of gastro-intestinal cancers

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Background:

Phthalates as excipients in drug products have gained interest as up to 50-fold higher levels of urinary phthalate metabolites have been observed in users of phthalate-containing drug products compared with non-users. This exposure is of concern, as phthalates are suspected endocrine disrupters and some phthalates have been associated with cancer development.

Aim:

This Ph.d. project aims to quantify phthalate exposure and explore whether there is an association with gastrointestinal cancers in Denmark throughout the period of 2004-2016.

Methods:

Studies in this project are based on registry data

Using an internal database held by Danish Medicines Authorities, quantifying phthalate exposure to the five different types of phthalates used in orally administered drug products is possible. The different types of phthalates are diethyl phthalate (DEP) dibutyl phthalate (DBP), Cellulose acetate phthalate (CAP), hydroxypropylmethylcellulose phthalate (HPMCP) and polyvinyl acetate phthalate (PVAP).

All patients with incident and histologically verified gastrointestinal cancers throughout the period 2008-2015 can be identified using the Danish Cancer Registry. The association between exposure to pharmaceutical phthalate exposure and risk of developing gastrointestinal cancers will be investigated using a matched case-control design. Baseline characteristics and identification of possible confounders will be obtained using National Prescription Registry, the National Patient Register, Registers in Statistics Denmark on educational level, and the Civil Registration System.

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