EUROmedicAT: Safety of Medication use in Pregnancy in Relation to Risk of Congenital Malformations

From 2011-03-01 to 2015-02-28, closed project

Project details

<table>
<thead>
<tr>
<th>Total cost:</th>
<th>Topic(s):</th>
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<td>EUR 3 956 151,60</td>
<td>HEALTH.2010.4.2-3 - Adverse Drug Reaction Research. FP7-HEALTH-2010-single-stage</td>
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<td>EU contribution:</td>
<td>Funding scheme:</td>
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<tr>
<td>EUR 2 996 100</td>
<td>CP-FP - Small or medium-scale focused research project</td>
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<td>Coordinated in:</td>
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<td>United Kingdom</td>
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Objective

A variety of complementary approaches are needed to evaluate safety of medicine use in pregnancy. To evaluate safety in relation to teratogenicity (capacity to cause malformations), population-based congenital anomaly registers, which are already networked across Europe (EUROCAT) with a common database, can provide a cost-effective mechanism which is as yet underexploited. The enormous population coverage of registers when combined gives sufficient statistical power for the identification of associations between specific drugs and specific malformations. This project will develop and test an efficient pharmaco-vigilance system for safety of drugs during pregnancy in relation to teratogenicity by (i) enhancing the information regarding drug exposure in the EUROCAT database, covering a total population of 3 million births 1995-2010, through linkage to electronic databases containing prescription information, and by linkage to chronic disease cohorts (ii) analysing the enhanced EUROCAT database in relation to four drug groups of public health concern - new antiepileptics, insulin analogs, SSRI antidepressants, and antiasthmatics - exposure to all of which is increasing in the pregnant population (iii) interrogating health care databases to monitor the effectiveness of drug safety recommendations and pregnancy prevention programmes through drug utilisation studies, and to provide an exposure profile for pregnant women (iv) conducting a scoping study of the implications for drug safety of growing internet use by pregnant women, in terms of access to safety information about teratogenicity, and access to drugs with teratogenic potential.

Related information

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