

Nordic multi-registry study of antiepileptic drug teratogenicity: the SCAN-AED study

A Population-based cohort study based on national registers from Norway, Denmark, Finland, Iceland and Sweden including more than 41 000 women using antiepileptic drugs in pregnancy

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BACKGROUND

It is unknown why antiepileptic drug (AED) exposure in pregnancy harms some but not other children. A significant limitation of previous studies has been statistical power when studying rare outcomes such as congenital anomalies and neurodevelopmental disorders.

OBJECTIVE

The SCAN-AED study links the Nordic population registers to examine

- the effects of in utero exposure of AEDs on congenital anomalies and neurodevelopmental disorders
- whether teratogenic effects of in utero AED exposure are influenced by, AED dose, folic acid supplements, co-medication, comorbidity and socioeconomic factors.

METHODS

We have linked individual level data in Norway, Sweden, Denmark, Iceland and Finland from

- the Medical Birth Registries
- the National Prescription Databases
- the Hospital Discharge Registries
- the National Statistical Agencies

Datafiles are stored and accessed from the Statistics Denmark research server

- Exposure is determined as ≥ 1 redeemed prescription of ≥ 1 AED between conception and birth for

RESULTS

The population consists of approximately 4 700 000 children, of whom 23 000 have been exposed to AED in pregnancy.

The study is approved by regulatory authorities including the Ethics committees and the Data inspectorate/ombudsman in all countries. Data files have been delivered and are being analyzed.



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