

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

INTRODUCTION

It is unknown why antiepileptic drug (AED) exposure in pregnancy harm some children and others not. A significant problem is that lack of statistical power hampers the study of new types of AEDs, the effects of co-medication, different doses and the interaction with comorbidity and socioeconomic factors.

OBJECTIVES

The SCAN-AED is a study in progress that aims to link population registers in four Nordic countries in order to study the effects of in utero exposure to AEDs on congenital malformations, neuropsychiatric disorders, long-term somatic morbidity and survival.

METHODS

We will link individual level data from the Medical birth registries, the National Prescription databases and The Patient registries to socioeconomic data from the National statistical agency (NSA) in Denmark, Norway, Sweden and Finland. Exposure are determined as ≥ 1 dispensation of ≥ 1 antiepileptic drug between conception and delivery. The pooled data will be stored and accessed from the research server of Statistics Denmark.

RESULTS

The included population will be around 4 700 000 children, of which 23 000 are AED exposed. The SCAN-AED study are approved by regulatory authorities (the Ethics committees, the Data inspectorate/ombudsman) in all countries. Data is ready for delivery in Finland. NordForsk and Helse Vest have funded the project.

DISCUSSION AND CONCLUSIONS

Joint Nordic registry studies can contribute cohorts large enough to study the complex causes of AED teratogenicity. To realize the project, the support from NordForsk and the NordMAN project is important, as well as cooperation between strong clinical and epidemiological research groups.