Otitis media and the possible association with early school performance – a prospective cohort study

Research protocol

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Rationale:
Otitis media affects 60% of Danish preschool children (1). Hearing loss is the most common complication, and known to result in development impairment by itself if longstanding and remitting (2). The hearing loss due to otitis media might therefore also have an effect on a child’s development and early school performance.

Background:
Otitis media is a common disease in childhood that can adversely affect cognitive and educational outcomes, however the literature in this area is equivocal (3). Regarding speech and language, a meta-analysis of prospective studies by Roberts et al only found no to very small associations of OME (otitis media with effusion) to speech and language development in most children (4). Yet, newer studies still show a negative association (5). The same applies for school performance, the literature is equivocal. Several skills and aspects of knowledge acquired at school have been studied. There is a tendency that older studies found a negative association (6–10) and that newer didn’t (11–16). Other recent studies have found mixed results (13,17). This can be explained by the increased consideration of associated factors in the newer studies, such as SES. Yet, many of these studies still have lacks, especially regarding sample sizes but also the absence of analysis of important associated factor. We believe our study with its large sample size and its possibility to consider for an increased amount of confounders will contribute with important results.
**Research objectives:**
Elucidate the association between parent reported otitis media and early school performance.

**Hypothesis:**
Primary hypothesis: *Parent-reported otitis media in early childhood affects the child's self-rated school skills the first years of primary school.*

**Method:**
The study design is a cohort study with prospective data collection, via computer assisted telephone interviews by trained interviewers.

**Source population:**
The population consists of children of pregnant women in Denmark in the period 1996-2003. 40% of all these pregnant women were willing to participate in the cohort. The women were recruited through their own doctor, at the first consultation after detection of pregnancy. Then followed a series of interviews during and after pregnancy, and biological samples were collected. This project uses the answers from the following interviews: 6-month interview, 18-month interview, 7-year interview and 11-year interview.

**Exclusion criterias:**
The following groups are excluded: Children diagnosed with Downs syndrome due to congenital anatomical abnormalities that increase the risk of acquiring otitis media. Children born before 34 weeks of gestation are excluded due to lung maturation treatment with betamethasone. This treatment is standard for premature babies born before 34 weeks of gestation in Denmark.

**Exposed:**
Exposed participants were defined by answering the 3rd, 4th and 5th interview, respectively, 6 and 18 months and seven years after birth with the answer "yes" to questions C130, D068 and Z021. Further is recurrent otitis media defined as answering "more than 3" to the questions C131 and D069 in Interview 3 and 4, where the number of otitis media events is requested.

**Outcome:**
Statistical analysis will be done on the outcome that is defined by answers to questions in the 7-year interview and the 11-year interview. The latter is answered by both child and parents. "Failure" outcome is also retrieved from answered questions.

**Power:**
Variables used for statistical analysis are answered with a response rate of 63%, equivalent to 57,282 people. Level of statistical significance defined as 0.05.
Calculating power with this sample size, we would be able to find a difference of 0.01 with a power/probability of 99%, provided a level of significance of 0.05.

We will conduct Bonferroni corrections to reduce the risk of type I errors by multiple calculations of significance.

**Data og analysis:**
For statistical calculation we will use SPSS 19 and SAS 9.4.
Outcome variables regarding school skills and school problems will be treated as categorical data.
Regression analysis will be used to adjust for confounders.
Sex and socioeconomic status (SES) will be stratified for.
In addition, we will take into account additional confounders found in the literature, assessed by DAG’s

**Ethical considerations:**
The cohort is pre-approved by biomedical ethics committee: case no. (KF) 01-471/94
There is approval from the Data Inspectorate for:
Primary cohort approved: case no. 2008-54-0431
7-year follow up approved: case no. 2004-41-4078

**Budget:**

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Time schedule:

Research investigator and supervisors:
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References:


