Study protocol: VIS-Flanders

Title	Implementation of a standard vestibular screening protocol for hearing-impaired children in Flanders.
Identifier	NCT05061069
Document Date	21.05.2024
Study type	Multicenter non-commercial interventional academic research
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Summary/Scientific background	Vestibular Infant Screening-Flanders (VIS-Flanders) is financially supported by the Research Foundation – Flanders (FWO). This project investigates the vestibular function in Flemish hearing- impaired children at the age of six months by using a screening tool. VIS-Flanders is the result of a cooperation between the department of Rehabilitation Sciences at the Ghent University and the Ear, Nose and Throat department at the Ghent University Hospital. A vestibular (balance) dysfunction can compromise the development of a child on many levels. One of the most important consequences of a vestibular dysfunction is the higher risk for motor deficits. In this context, a highly vulnerable group comprises children with a hearing loss. Because of the close anatomical relationship between the auditory (hearing) and vestibular (balance) organs, it seems evident that an inner ear disease may affect not only the auditory, but also the vestibular function. Whereas vestibular and motor assessment in hearing-impaired children is standard of care in the Ghent University Hospital, this is currently not a standard component in the diagnostic follow-up of hearing-impaired children in other care centres in Flanders. Therefore, vestibular deficits in hearing-impaired children currently often go unnoticed, giving rise to associated disorders such as a delayed motor development, behavioral disorders, etc. The implementation of a vestibular screening in hearing-impaired babies of six months old will timely discover vestibular problems to limit the impact on the (motor) development. The cervical vestibular evoked myogenic potential (cVEMP) technique will be used as a vestibular screening tool. Flanders is the first region worldwide that will implement a vestibular screening. All official Flemish reference centres of Kind en Gezin (Child and Family) will participate in this project.

Objectives	The main objective of this TBM-project is to limit the impact of a vestibular dysfunction on the motor, cognitive and psychosocial development of hearing-impaired children. In order to achieve this goal, we aim to implement a standard vestibular screening protocol in Flanders for all children with a hearing loss, detected by a 'refer' on the neonatal hearing screening (Kind & Gezin) and confirmed by a diagnostic hearing evaluation in one of the reference centres in Flanders. The vestibular screening would be scheduled at the age of 6 months in order to expedite the early detection of vestibular deficits and subsequent referral for rehabilitation.
Design & methodology	Multicenter non-commercial interventional academic research. The aim of the TBM-project is to add a vestibular screening to the existing auditory screening programme (MAICO test). The following steps will be performed to guarantee an accurate vestibular follow-up in Flemish hearing-impaired children: ✓ In case of a 'refer' on the second MAICO test, Kind en Gezin (Child and Family) will refer the child to the reference centres of Kind en Gezin in Flanders. ✓ These reference centres will perform a diagnostic hearing test (brainstem evoked response audiometry: BERA) to confirm the permanent hearing loss (standard of care). ✓ Each child with a confirmed hearing loss (BERA 'refer') will be subjected to a vestibular screening in that specific reference centre at the age of six months. The cervical vestibular evoked myogenic potential (cVEMP) technique will be used. ✓ In case of a refer on the vestibular screening (cVEMP 'refer'), the reference centres will refer the child for motor assessment and, if necessary, for rehabilitation.
Number of study patients and duration	From June 2018 until June 2021 approximately 360 patients will be tested in all participating centers in Flander and Brussels (in the end, 301 infants were screened, 47 were excluded, and 254 infants were included in the study.
Type of patients	Children with a confirmed hearing-loss about the age of 6 months old (between 0 and 1 year old)
Statistical Analysis Plan	Statistical analysis will be completed with SPSS software (IBM, version 27.0, Armonk, NY). On subject level, abnormal screening results indicate abnormal responses in at least 1 ear, and the degree of hearing loss will be categorized according to the worst ear in case of bilateral hearing loss. The two-tailed Fisher's Exact test will be used to evaluate the association between screening results and possible predisposing factors. On ear level, data will be analyzed more in-depth by means of generalized estimating equations, which takes the clustered data structure (ie, 2 ears within 1 child) into account and provides a robust estimator of the covariance matrix. Odds ratios (OR) with 95% confidence intervals (95% CI) will be reported. The significance level (ie, two-tailed) will be set at $P < .01$ to correct for multiple testing.