

Developmental Evaluation of Children: Impact and Benefits of Early hearing screening strategies Leiden

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What is the effect of the distraction hearing screening strategy compared to the neonatal hearing screening strategy on speech and language development and other developmental parameters in children with permanent childhood hearing impairment (PCHI...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31419

Source

ToetsingOnline

Brief title

DECIBEL-study

Condition

- Hearing disorders

Synonym

permanent childhood hearing impairment

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Willem-Alexander Kinderfonds;Het Heinsius Houbolt fonds

Intervention

Keyword: Development, Distraction hearing screening, Neonatal hearing screening, Permanent Childhood Hearing Impairment (PCHI)

Outcome measures

Primary outcome

Compare Dutch hearing screening strategies (Strategy A and B) in their consequences on speech-language-, socio-emotional and general development in children with PCHI at the age of four.

Secondary outcome

Causes of PCHI (optional: if parents desire molecular diagnostic investigation and/or viral (CMV) investigation for PCHI-etiology, a fresh blood sample can be taken or dried blood sample (Guthrie-card) can be recalled), age of detection of PCHI, health care costs and quality of life will also be compared.

Study description

Background summary

The distraction hearing screening strategy (Strategy A, screening at 9 months) has been gradually replaced in The Netherlands by the neonatal hearing strategy (Strategy B, screening within 2 weeks of birth). The aim of the neonatal hearing screening strategy at implementation was early diagnosis of hearing loss and early intervention. Early diagnosis and intervention is expected to lead to an improved outcome in speech and language development, with as secondary effects; improved chances for better social, emotional and cognitive development.

Study objective

What is the effect of the distraction hearing screening strategy compared to the neonatal hearing screening strategy on speech and language development and other developmental parameters in children with permanent childhood hearing impairment (PCHI) at the age of 4 years?

Secondary objectives: Comparison of: moment of diagnosis of PCHI, causes of PCHI, Quality of life and health care costs. This study will provide the evaluation of the neonatal hearing screening strategy in The Netherlands.

Study design

Retrospective, observational, pseudo-randomized study. The region of birth and the date of birth determine assignment to the hearing screening strategy: Strategy A or B.

Assessments in both strategies: speech-language development, general and socio-emotional development, quality of life.

Intervention:

Two different hearing screening strategies offered to children (distraction (=A) or neonatal screening (=B)).

The interventions differ in type of hearing screening and age of the child at hearing screening.

Study burden and risks

Burden: Answering the questionnaire, the visit of the researcher at the child's home or the visit of the child and his/her parents to the Audiological Centre and extensive physical examination by investigator. Risks for the participants: none. Benefits for the individual: adequate information on speech and language development and general developmental parameters.

Benefits in general: Information on possible benefits and problems of the neonatal hearing screening. This study will provide information on the effects of early detection, insight in the possible causes of PHI in children and information for improvement of the newborn hearing screening.

Contacts

Public

Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL

Scientific

Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Children born between 1-1-2003 and 31-12-2005

Children who were offered a Dutch hearing screening in the first year of life

Children with permanent childhood hearing impairment (Definition: hearingloss of at least 40dB in the better ear)

Exclusion criteria

Those who do not fulfill the inclusion criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated):	01-11-2007
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18788.058.07