

Prevalence of excessive cerumen in adults with an intellectual disability

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By this study we*d like to determine the prevalence of excessive cerumen in people with an intellectual disability. Besides we*d like to study whether there is an correlation to sexe, age, type of residence, degree of intellectual disability,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	External ear disorders (excl congenital)
Study type	Observational invasive

Summary

ID

NL-OMON33415

Source

ToetsingOnline

Brief title

earwax

Condition

- External ear disorders (excl congenital)

Synonym

cerumen, earwax

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: betreffende instellingen voor verstandelijk gehandicapten

Intervention

Keyword: earwax, intellectual disability, prevalence

Outcome measures

Primary outcome

The results of otoscopy are divided into 2 groups: 1. otoscopy shows no tympanic membrane or only a marginal strip of the tympanic membrane. 2. remaining outcomes. These are the results where no cerumen is seen, or only a minimal cerumen up to substantial.

We describe both ears.

Secondary outcome

The following information is registered: sex, age, type of residence, degree of intellectual disability, syndrome of Down, hearing devices, frequency of rinsing the ears, frequency of infections of the ear and incidence of eczema of the ear.

Study description

Background summary

Everybody produces cerumen, also known as earwax. Sometimes the cerumen can become excessive and that involves several complaints such as itching, pain, hearing loss, tinnitus and dizziness. These complaints can lead to mood disorders and social withdrawal.

In the daily practice it seems that excessive cerumen occurs more often in people with an intellectual disability. Because of this and the fact that excessive cerumen has considerable consequences for hearing and behaviour we'd like to study the prevalence of excessive cerumen in a Dutch adult population.

Study objective

By this study we'd like to determine the prevalence of excessive cerumen in

people with an intellectual disability. Besides we*d like to study whether there is an correlation to sexe, age, type of residence, degree of intellectual disability, syndrome of Down, hearing devices, frequency of rinsing the ears, frequency of infections of the ear and incidence of eczema of the ear.

Study design

The study is describing cross-sectional observational.

Study burden and risks

The investigators are competent in examine the outer ear by otoscopy. Otoscopy is a mild examination with minimal risks and usely takes about 5 minutes. During the examination there will be assistance of a person that is close related to the client to comfort the client and give explanation if necessary to the client. The examination will take place either at the medical practise or at the client*s home.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

intellectual disability

living either in communities or institute

Exclusion criteria

abnormal anatomy of the ear

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-07-2009

Enrollment: 648

Type: Actual

Ethics review

Approved WMO

Date: 08-07-2009

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26910.078.09