

Pain sensitivity in children and adults with Down syndrome: do they have altered pain thresholds and tolerance?

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The aim of this experimental study is to find out whether children and young adults with the DS have an altered pain sensitivity in comparison with children and young adults without cognitive impairment.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30552

Source

ToetsingOnline

Brief title

Pain sensitivity in children with Down syndrome

Condition

- Other condition
- Structural brain disorders

Synonym

Down syndrome and pain sensitivity

Health condition

verstandelijk handicap

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Child, Pain sensitivity, Trisomy 21

Outcome measures

Primary outcome

Detection threshold warm, pain threshold heat pain, pain report to different heat and heat (pain) stimuli.

Secondary outcome

none

Study description

Background summary

Children with Down syndrome (DS), do show pain behavior. However, their responses to pain are less vigorous than in children without mental retardation. Because of this, it is generally believed that these children are less sensitive to pain. Evidence to accept this assumption, however, is lacking. Perhaps these children are more sensitive to pain, but because of their handicap they do not have the ability to respond quickly or more vigorously. Recently, however, it was shown that adults with the Down syndrome had lower pain thresholds than adults without cognitive impairment, suggesting greater pain sensitivity. Whether this finding can be contributed to the Down syndrome or whether this is due to a lower cognitive functioning in the Down people remains unclear.

Study objective

The aim of this experimental study is to find out whether children and young adults with the DS have an altered pain sensitivity in comparison with children

and young adults without cognitive impairment.

Study design

Experimental study using balanced groups

Intervention

All study subjects will undergo thermal (pain) stimuli.

Study burden and risks

no risks

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)

Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Index group: Trisomy 21, (biological age 10-12 and 20-22 year-old). Both groups have a social and communicative adaptation behaviour corresponding with that of children without CI of ≥ 7 years, i.e. total score on the Vineland-Z social domain ≥ 97 and a total score on the Vineland-Z communication domain ≥ 93

Reference subjects: children with a biological age of 7-12 years and young adults with a biological age of 20-22 years.

Exclusion criteria

Index group: not able to tell what pain is and when they suffered pain, not responsible to reproduce the instructions given for testing, any record of behavioural or language problems, or use of anti-epileptics, anti-depressives, or spasmolytics.

Reference groups: mental handicap, or use of anti-epileptics, anti-depressives, or spasmolytics.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	96

Type: Anticipated

Ethics review

Approved WMO

Date: 31-07-2007

Application type: First submission

Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL11943.000.06