

Know Their Pain | Down Study 2011: Quantitative Sensory Testing and pain behaviour of subjects with Down*s syndrome compared to healthy controls

Published: 12-04-2010

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To compare discrimination ability for touch and temperature between subjects with Down*s syndrome and healthy controls. To compare thermal pain thresholds between subjects with Down*s syndrome and healthy controls

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational non invasive

Summary

ID

NL-OMON36235

Source

ToetsingOnline

Brief title

QST in subjects with Down's syndrome

Condition

- Chromosomal abnormalities, gene alterations and gene variants

Synonym

Down's syndrome, Trisomy 21

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, Stichting Erasmus Fonds Pijnbestrijding

Intervention

Keyword: Down's syndrome, Pain sensitivity, Quantitative Sensory Testing

Outcome measures

Primary outcome

- Sensory testing part 1: Correct sensations of cold, warmth, light touch, and sharpness.

- Sensory testing part 2: Correct sensations of touch (Neuropen) and warm / cold (Rolltemp)

- Sensory testing part 3: Detection threshold (touch) by Von Frey hairs.

Detection and pain thresholds (warm and cold) in degrees Celsius (Thermal Sensory Analyzer).

Secondary outcome

Not applicable

Study description

Background summary

Down's syndrome is the number one cause of congenital intellectual disability in the Netherlands: each year about 275 children are born with Down's syndrome. It is important to study the pain experience and pain expression of those children. Pain assessment and -treatment in intellectually disabled children can perhaps be more effective and more tailor-made, when the transmission of nociceptive stimuli in those children is better understood. Quantitative sensory testing, with the Thermal Sensory Analyzer, proved promising in children and adults. However, there is still little experience with this test in intellectually disabled children such as children with Down's syndrome.

Study objective

To compare discrimination ability for touch and temperature between subjects with Down*s syndrome and healthy controls.

To compare thermal pain thresholds between subjects with Down*s syndrome and healthy controls

Study design

Observational study

Study burden and risks

The subjects will be tested at home (duration 2 hours). The measurements are risk free with minimal burden. One saliva sample of 2 mL will be collected. Parents are asked to complete three questionnaires. Moreover, this project serves as a starting point for the evaluation of pain in other groups of intellectually disabled individuals.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
NL

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

Down*s syndrome group:

- Confirmed trisomy 21
- Age 8 to 30 years ;Control group:
- Sibling of participant with Down*s syndrome
- Age 8 to 30 years

Exclusion criteria

- Developmental age lower than 5 years
- Insufficient understanding of the concepts of warm and cold sensation
- Diagnosis of migraine
- Treatment with antidepressants
- Treatment with anticonvulsants
- Treatment with analgesics <24 hours before study visit

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped

Start date (anticipated):	01-11-2010
Enrollment:	156
Type:	Actual

Ethics review

Approved WMO	
Date:	12-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	26-09-2011
Application type:	Amendment
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	NL31714.078.10