The dichotomization of pediatric stroke outcome; comparison of a new composite scale with frequently used outcome measures

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The objective of this study is to determine whether the dichotomization in good and poor outcome by the composite scale, corresponds better with the parents' and doctor's opinion on the outcome than the PSOM. The composite scale willl be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31696

Source
ToetsingOnline

Brief title
The dichotomization of pediatric stroke outcome

Condition

- Central nervous system vascular disorders

Synonym
pediatric ischaemic stroke; stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,Drs. M.M.M. Bulder wordt financieel ondersteund door het Wilhelmina Onderzoeksfonds.

Intervention

Keyword: children, composite scale, outcome measure, pediatric stroke

Outcome measures

Primary outcome

1. The Pediatric Stroke Outcome Measure (PSOM). At the completion of the examination a deficit severity score ranging from 0 (no deficit) to 2 (severe deficit) is assigned for each of five spheres: right sensorimotor (including motor, visual, hearing and somatosensory function), left sensorimotor, language production, language comprehension, and cognitive and behavioral performance. The patient is assigned an overall Deficit Severity Score of normal (0=normal function), mild (1/2=minimal to mild impairment, normal function), moderate (1=decreased function), or severe (2=loss of function) for each assessment, based on the combination of scores in the individual spheres of the PSOM.

2. A two- item parental questionnaire.

Question 1: *does your child need extra help with day-to-day activities compared with other children of the same age?*

Question 2: *does your child attend special schooling?*

Outcome is, based on the PSOM score and on the questionnaire, classified into two categories: *good* outcome and *poor* outcome.

Secondary outcome

1. Visual Analogue Scale: parent*s report (score 0-10).

2. Visual Analogue Scale: doctor*s report (score 0-10).

3. PedsQL: health related quality of life.

- Parent Reports for Ages 2-4, 5-7, 8-12, and 13-18 (Total score 0-100)

- Patient Self-Reports for Ages 5-7, 8-12, and 13-18 (Total score 0-100)

4. Modified Rankin Scale: degree of disability (score 0-6).

5. Short neuropsychological examination.

Study description

Background summary

Clinical research in childhood stroke requires a well-validated and standardized childhood stroke outcome measure that allows a meaningful and reliable dichotomization in *good* or *poor* outcome. Such a measure should ideally cover several levels of functioning, and reflect both objective neurological deficits and subjective quality of life. The PSOM is a frequently used childhood stroke outcome measure. However, the PSOM has several limitations: 1. cognitive functions after childhood stroke are not taken into account; 2. there is a strict dichotomisation in the PSOM, in which children with only mild deficits without restrictions in daily activities are classified as 'poor outcome'.

This study will determine ischaemic stroke outcome in children by using a composite measure. This composite measure, based on the Pediatric Stroke Outcome Measure (PSOM), combines findings at neurological examination with a two-item parental questionnaire. The two-item questionnaire includes a question on school performance, since one third of the surviving patients attend a school for special education in contrast to the 5% of children in the general population who attend schools for special education. Outcome will be based on the PSOM and the parental questionnaire and defined as *good* or *poor*. This dichotomization will be compared with the results obtained from other outcome measures, like the modified Rankin Scale, PedsQL and a short neuropsychological examination.

The proposed study on the dichotomization of pediatric stroke outcome closely relates to a research project starting in the near future. This research project investigates the association between stroke outcome and perfusion

deficits in children and young adults with arterial ischaemic stroke. Since the proposed study assesses a new composite scale, this might have influence on defining the outcome measure of pediatric stroke in future stroke research projects.

Study objective

The objective of this study is to determine whether the dichotomization in good and poor outcome by the composite scale, corresponds better with the parents' and doctor's opinion on the outcome than the PSOM. The composite scale willl be compared with other frequently used outcome measures.

Study design

Outcome is, based on the PSOM and the parental questions, classified into good outcome or poor outcome. The result of dichotomisation will be compared with the result of dichotomisation, as used by DeVeber and Delsing.

Second, in order to test the accuracy of the composite score, it will be compared with the following validated measures:
- Visual Analogue Scales (doctor*s report and parent*s report)
- PedsQL (child*s report and parent*s report)
- Modified Rankin Scale
- Short neuropsychological examination

Since these measures can not be regarded as the *gold standard*, the new composite scale will not be validated in this study. Therefore, the proposed study will be descriptive, and must be regarded as a first step towards a new outcome measure for children after ischaemic stroke.

Study burden and risks

There are no risks for the patient and his/her parent(s) when participating in this study. The patient and his/her parent(s) have to visit the hospital only once. This visit will take only 2.5 hours.

Contacts

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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

- age 1 month - 18 years at the time of stroke
- age between 2 and 19 years at time of investigation
- the patients have been treated in the UMCU for ischaemic stroke (arterial ischaemic stroke or sinovenous trombosis) between 2000 and 2007

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2008
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	12-02-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL19646.041.07