The clinical value of measuring gastric emptying in children with a severe generalized cerebral palsy

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The objective of the study is to determine what the clinical value is of measuring GE of liquids in 50 SMID children. The primary study parameter is how often DGE of liquids occurs in this study group. Secondary study parameters include...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON30780

Source
ToetsingOnline

Brief title
GECC (Gastric Emptying in Children with severe generalized Cerebral Palsy)

Condition

- Appetite and general nutritional disorders

Synonym
Delayed gastric emptying

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: Breath Test, Cerebral Palsy, Child, Gastric Emptying

Outcome measures

Primary outcome

The primary study parameter is how often DGE of liquids occurs in SMID

children.

Secondary outcome

Reproducibility of the measurement will be studied in 10 children. Differences

in GE in children with and without GORD and with and without a gastrostomy are

also studied.

Study description

Background summary

Children with severe motor and intellectual disabilities (SMID) suffer from much co-morbidity among which digestive problems such as gastro-oesophageal reflux disease (GORD) and constipation. Impaired motility is often the basis of these disorders and this is also true for delayed gastric emptying (DGE). The latter causes any number of symptoms such as feeling bloated, early satiety, nausea and can even worsen existing GOR. Because of these complaints the eating experience is very unpleasant and this negatively impacts nutritional state.

Gastric emptying (GE) hasn*t been studied much in SMID children and existing methods of measuring GE like scintigraphy aren*t suitable for children because of the long time spent before a gamma camera and the burden of radiation. The last couple of years the 13C breath test is being used more and more in research. It is a very suitable test for these children because of its simplicity, lack of radiation exposure and because children do not have to actively cooperate.

Study objective

The objective of the study is to determine what the clinical value is of measuring GE of liquids in 50 SMID children. The primary study parameter is how

often DGE of liquids occurs in this study group. Secondary study parameters include reproducibility of the measurement, but also the influence of GORD and a gastrostomy on GE will be studied.

Study design

It is a non-therapeutic intervention study in which in 50 children GE of liquids will be measured using the 13C breath test. In 40 children GE will be measured once, in the remaining 10 children the test will be performed twice with an interval of one week. During the measurement a testmeal will be given after fasting for 3 hours and subsequently breath samples will be collected during the next 4 hours on regular intervals.

Intervention

If participating children take medication that effects gastric emptying (Domperidon and Prepulsid), we ask the parents to temporarily withhold these for three days prior to the measurement.

Study burden and risks

The burden of this study is being kept to a minimum by keeping the time that children can*t eat or drink as short as possible. If there are any clues of active resistance the measurement will be stopped immediately. Participants in this study are not at risk of any health hazards since the substrate 13C is completely safe.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Severe motor disability (GFMCS level of 4 or 5)
Mild to severe mental handicap (IQ of 55 or less)
Age 1-18 yrs

Exclusion criteria

Not being able to stop medication that influences gastric emptying
Not being able to drink the testmeal (milk) due to swallowing problems without a gastrostomy present.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-10-2008
Enrollment:	50
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	28-11-2007
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	NL15937.000.07