Validity and reliability of test weighing (weighing before and after a feed) in term and preterm neonates according to a standardized validated test weighing technique in clinical practice.

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This study aims to assess the degree of accuracy of test weighing in order to determine whether or not test weighing is a useful method in clinical practice.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38895

Source
ToetsingOnline

Brief title
Reliability of test weighing in neonates

Condition

- Appetite and general nutritional disorders

Synonym
milk intake breast feeding, test weighing

Research involving
Human

Sponsors and support

Primary sponsor: IJssellandziekenhuis
Source(s) of monetary or material Support: er is geen financering;onderzoek wordt in werktijd uitgevoerd

Intervention

Keyword: Estimate milk intake, Measuring milk intake, Test weighing

Outcome measures

Primary outcome

The primary outcome of this study is the degree of accuracy of the weighing

result set against the actual milk intake.

Secondary outcome

Will devices, which are connected to the neonate during test weighing (monitor

wires, pulse oximeter, infusion lines), affect the accuracy of the test

weighing?

Study description

Background summary

Weighing before and after breastfeeding (test weighing) is a commonly used method to estimate milk intake in neonates. There is, however, no consensus on the reliability of this method of test weighing. Questioning the reliability of test weighing has major consequences for the guidance of women breastfeeding sick or premature neonates, since there are no other clinically useful methods to estimate breastmilk intake.

Study objective

This study aims to assess the degree of accuracy of test weighing in order to determine whether or not test weighing is a useful method in clinical practice.

Study design

This study is an observational study.
Neonates who are being fed by bottle, are swaddled en weighed before and immediately after regular feeding by a blinded investigator. The initial body weight of the neonate, measured right before feeding, is subtracted from the body weight of the infant after feeding. This calculation provides an estimate of the milk intake of the neonate.
The actual amount of milk (in milligrams) drunk by the neonate, is measured consecutively. For this purpose, the milk bottle is weighed before feeding (measurement 1), and immediately after feeding the same bottle with the rest of the milk is weighed again (measurement 2).
The result of measurement 2 is subtracted from the result of measurement 1.This calculation indicates the actual amount of milk consumed in milligrams. For this measurement, it is assumed that 1 milligram of milk equals1 milliliter of milk.
Weighing takes place according to a standardized validated weighing method. Before weighing the neonates, the scales, which are digital medical class III baby scales, are calibrated according to the Dutch Metrology Act. The accuracy of the scales is assessed by means of calibration; meaning in this case determining the standard deviation of repeated measurements with standard weights.

Study burden and risks

The risks associated with participation in the study may reasonably be regarded as negligible.
The neonate is weighed in the room where it is resides during hospitalization and the mobile baby scales are brought to the neonate. The neonate is weighed as it is, additional dressing or undressing is not required. The infant is placed on the scales for weighing twice: before and after feeding.
The weighing takes about 1 to 2 minutes per weighing, thus in total about 4 minutes. Each neonate can participate once in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants, admitted to the neonatal ward of the IJsselland Hospital, a general hospital in the Netherlands.
The infants meet the following criteria: postconceptional age on day of study between 34 and 44 weeks, with or without feeding tube, iv drip and infusion splint, monitor lead wires.
The infants are bottle fed mothermilk or formula with volumes at least 10 ml

Exclusion criteria

Clinically unstable neonates, assessment of clinical stability by the attending pediatrician.
Neonates who required continuous connection to monitors
Neonates who are not able to drink from bottle
Exclusively breastfed neonates

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-12-2013
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	15-11-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL45687.098.13