Solid foods in Preterm infants and the effect On Obesity in the Netherlands - Timing of complementary feeding in preterm infants and the effect on obesity

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To analyze the effect of early (12 weeks corrected age) versus late (17 weeks corrected age) introduction of complementary feeding on obesity at the age of 2 years in preterm infants. Furthermore, the effect of complementary feeding on body...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53076

Source
ToetsingOnline

Brief title
SPOON study

Condition

- Other condition

Synonym
obese, overweight

Health condition

obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Nutricia,Ziekenhuis Gelderse Vallei Ede;samenwerkingsbijdrage vanuit Nutricia

Intervention

Keyword: BMI, complementary feeding, premature infant, weaning

Outcome measures

Primary outcome

BMI at the age of 2 years (association)

Secondary outcome

1) Body composition

2) Eating behavior of the child by using and tolerating complementary feeding

3) Quality of life

4) Allergies using the SCORAD

5) Microbiome

Study description

Background summary

Limited evidence is available about the optimal age of the start of complementary feeding in preterm infants and implications for both short and long term health. Complementary feeding is defined as the introduction of non-(breast) milk foods or nutritive liquids when milk alone is no longer sufficient to meet all nutritional requirements. In this period, there is a gradual transition to eating family foods. Timely introduction of complementary feeding during infancy is necessary for both nutritional and developmental reasons. Complementary feeding is associated with major changes in both macronutrient and micronutrient intake. Early complementary feeding in term infants is suggested to be a risk factor for childhood obesity. Childhood

obesity is associated with major health risks. There is evidence that overweight youth are at increased risk of remaining overweight. However, these results concern term-born infants and cannot be directly translated to preterm infants. To determine correlations between the start of complementary feeding and obesity it is important to perform this study.

Study objective

To analyze the effect of early (12 weeks corrected age) versus late (17 weeks corrected age) introduction of complementary feeding on obesity at the age of 2 years in preterm infants. Furthermore, the effect of complementary feeding on body composition, eating behaviour, quality of life, and microbiome will be determined.

Study design

Randomized parallel group open-label controlled intervention study.

Intervention

The intervention group will start complementary feeding at 12 weeks corrected age. The control group will start complementary feeding at the corrected age of 17 weeks. The pattern and structure of the complementary feeding will be according to the advice of the welfare centre in the Netherlands.

Study burden and risks

The burden and risks associated with participation to this study are minimal. The benefits of starting early complementary feeding are well described by King. King suggested that it is not necessary to wait for lip seal to develop and tongue protrusion to diminish before weaning. In fact, premature children may only mature with the aid of weaning. Furthermore, some infants may develop rapidly with increasingly textured food. There is evidence for not starting complementary feeding before 3 months corrected age, because motor development necessary for safe and successful transition to solid foods may not have been achieved until at least 3 months. For that reason, none of the children will start complementary feeding before 3 months of age corrected age. From data on term infants it seems likely that the later a preterm infant is introduced to new tastes, the less likely they are to accept a wide variety of foods. King also puts forward that there is no evidence that preterm infants are more likely to develop atopic diseases due to immaturity of the gut and immune system.

For the primary outcome we would like to determine BMI at the age of 2 years. Additionally, we would like to determine BMI before the start of complementary feeding and at the age of 1 year. Ideally, we would like to combine these

hospital visits with regular visits in the follow-up of the preterm infants. Furthermore, we would like to have extra information on the microbiome requiring faeces samples. Faeces samples are taken at three different time points in both groups. Parents are asked to collect the faeces at home.

In conclusion, we would like to obtain information before the start of complementary feeding and at the age of 1 and 2 years. This means three extra hospital visits, depending on the arrangement for the follow-up of preterm infants in the different hospitals. Whenever possible, visits for the study will be combined with regular visits. The risks associated with this study are minimal. There will be no benefit for the individual participating in this study. To determine correlations between height, weight, BMI, eating behaviour and microbiome in preterm infants it is important to perform this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

premature infants, born between 30 and 35 6/7 weeks gestational age., preterm infants, born between 37 and 42 weeks gestational age.

Exclusion criteria

• Diseases interfering with stable growth
• Dysmaturity
• Intestinal disorders
• Bronchopulmonary dysplasia (BPD)
• Kidney disorders
• Congenital heart disease with hemodynamic consequences
• Severe cow milk allergy
• Congenital anomalies ENT area, esophageal and or tracheal, needing operative correction
• Syndromal disorders
• Intra ventricular hemorrhage grade III or IV
• No motivation of parents
• No informed consent, Term born children:
- Small for Gestational Age (SGA) (- Diseases interfering with stable growth
- Intestinal disorders (necrotizing enterocolitis needing surgery, short bowel syndrome, hirschsprung disease, inflammatory bowel disease)
- Moderate and severe bronchopulmonary dysplasia (BPD) defined according to the international criteria
- Kidney disorders
- Congenital heart disease with hemodynamic consequences
- Severe cow milk allergy (Samson score > 3)
- Congenital anomalies Ear Nose Troat (ENT) area, esophageal and or tracheal, needing operative correction (e.g. cheilognatopalatoschizes, esophageal atresia)
- Syndromal disorders (e.g. trisomie 21, PraderWilli)
- Intra ventricular hemorrhage grade III or IV
- No motivation of parents
- No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2016
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	29-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26861
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50601.029.14
Other	www.trialregister.nl en www.clinicaltrials.gov. Studie is aangemeld. Identificatienummers volgen.