Solid food in preterm infants and the effect on obesity in the Netherlands: timing of complementary feeding in preterm infants

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

Summary

ID

NL-OMON26861

Source
NTR

Brief title
SPOON

Condition

- Other condition

Synonym
Overweight and obesity

Health condition

preterm infants, complementary feeding, obesity

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuis Gelderse Vallei Ede
Source(s) of monetary or material Support: Nutricia Research Foundation

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome
The prevalence of overweight/obesity determined by measuring the BMI at the corrected age of 2 years, according to the IOTF cut-off value

Secondary outcome
- Overweight (including obesity): to determine the effect of early versus late introduction of complementary feed on the BMI, according to the IOTF cut-off values at 1 year.

- Eating behavior and tolerating complementary feeding: to determine if early introduction is correlated with less eating problems in comparison to introduction the late introduction, by using the Baby Eating Behaviour Questionnaire (BEBQ) and Child Feeding Questionnaire (CFQ).

- Eating behavior and tolerating complementary feeding: to determine if term born infants (control group) have less eating problems in comparison to preterm infants before the start of complementary feeding, by using the Baby Eating Behaviour Questionnaire (BEBQ)

- Growth parameters (weight, length, head circumference, BMI, weight-for-age, length-for-age, head circumference-for-age): comparing the growth parameters of preterm infants with term infants before the start of complementary feeding, at 1 year and at 2 years

- Health Related Quality of life (HRQoL): to evaluate the difference in HRQoL between early versus late introduction of complementary feeding, by using The Infant Toddler Quality of Life (ITQoL) Questionnaire or Pediatric Quality of Life Inventory (PedsQL).

- Ages and Stages Questionnaire (ASQ): to evaluate the difference in development between early versus late introcution of complementary feeding, by using the ASQ at the age of 1 and 2 years.

- Allergy/Atopic: to evaluate if the incidence of allergies is different between early versus late introduction of complementary feeding, by using the SCORAD.

- Microbiota: to evaluate if the microbiota change due to the introduction of complementary

feeding

Study description

Background summary

Optimal timing of introduction of complementary feeding during infancy is necessary for both nutritional and developmental reasons. Limited evidence is available about the optimal age of solid food introduction in preterm infants and implications for both short and long term health, including overweight and obesity.

Study objective

The main objective of this study is to analyze the effect of early (12 weeks corrected age) versus late (17 weeks corrected age) introduction of complementary food (weaning) on the prevalence of obesity at the age of 2 years in preterm infants. Overweight (including obesity) is determined by measuring the BMI, according to the IOTF cut-off values. Preterm infants are included when born between 30 and 36 weeks of gestational age.

Study design

Multicenter randomized controlled trial

Intervention

Randomization between starting with complementary feeding at 12 weeks corrected age and 17 weeks corrected age

Study burden and risks

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, and eating behaviour in preterm infants it is important to perform this study in this age category.

Contacts

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Eligibility criteria

Age
Newborns
Newborns
Babies and toddlers (28 days-23 months)
Babies and toddlers (28 days-23 months)

Inclusion criteria

For preterm infants

1. Preterm infants born at gestational age between 30 and 36 weeks

2. Written informed consent from both parents, or legal representive

For control groep

1. Term born infant (born between 37 and 42 weeks of gestational age)

2. Written informed consent from both parents, or legal representive

Exclusion criteria

1. Small for Gestational Age (SGA) 2. Diseases interfering with stable growth 3. Twins or triplets 4. Intestinal disorders (necrotizing enterocolitis needing surgery, short bowel syndrome, hirschsprung disease, inflammatory bowel disease) 5. Moderate and severe bronchopulmonary dysplasia (BPD) defined according to the international criteria 6. First degree family member with celiac disease 7. Kidney disorders 8. Congenital heart disease with hemodynamic consequences 9. Severe cow milk allergy 10. Congenital anomalies Ear Nose Troat (ENT) area, esophageal and or tracheal, needing operative correction 11. Syndromal disorders 12. Intra ventricular hemorrhage grade III or IV 13. No motivation of parents 14. No informed consent

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2016
Enrollment:	600
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	03-02-2016
Application type:	Not applicable
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

ID: 53076
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4799
NTR-old	NTR4939
CCMO	NL50601.029.14
OMON	NL-OMON53076

Study results

Summary results
N/A