Randomised, double-blind, controlled, multi-country and multi-centre intervention study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29128

Source
Nationaal Trial Register

Brief title
IDea

Health condition

- Healthy toddlers, 18 - 36 month old
- growing up milk
- Vitamin D level
- Iron level

Sponsors and support

Primary sponsor: Danone Research – Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research – Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

The primary outcome parameter in this study is the change in serum SF concentrations after 20 weeks of study product consumption.

Secondary outcome

1. Prevalence of ID and IDA:

A. ID is defined as SF <12 µg/l;

B. IDA is defined as blood haemoglobin (Hb) <110 g/l, combined with SF <12 µg/l.

2. Biochemical assessments of vitamin D status: change from baseline in serum 25(OH)D concentrations;

3. Prevalence of vitamin D deficiency, defined as serum 25(OH)D < 50 nmol/l.

Study description

Background summary

The study will consist of a 20-weeks intervention period and 2-weeks follow up period. After parents have signed for informed consent, a venous blood sample will be taken (10 ml) from subjects eligible for participation. Subject height and weight will be measured and the parents will be asked questions about their child's demographic- and socio-economic characteristics, day care centre attendance and medical history. The parents will finally be asked to complete a food questionnaire. Eligible subjects will then be randomly allocated to receive either the test study product or the control study product for a double-blind period of 20 weeks. After one, five and fifteen weeks, planned telephone contact will be made with the parents, during which study product compliance and the completion of the diary will be discussed. These diaries, which are to be completed by the parents daily, will consist of questions on intake of study product, adverse events, stool consistency and the use of medication. Halfway through the study (10 weeks after study entry) parents will be asked to visit the study centre in order to collect new study product and to discuss potential issues and challenges faced during the study. During this visit the height and weight of the subject will also be measured. Shortly before the final study visit, telephone contact will take place to check if the subject is ill or has been recently vaccinated. The visit will be postponed for 2 weeks, with ongoing use of study product, in case this is necessary. After 20 weeks (or after 22 weeks in cases where this is necessary), subjects will be asked to come back to the study centre. During this final visit a venous blood sample will be taken (10 ml), height and weight will be measured, subject diaries and left over study product will be collected, and parents will be asked to complete a food questionnaire. Final telephone contact will take place 2 weeks after intervention, at 22 weeks.
Subjects should not change their supplementation habits during the study.

The baseline study visit may coincide with an elective, non-emergency surgery (e.g. urological surgeries, inguinal or umbilical hernia operations or (molar) teeth extractions). The baseline venous blood draw may then be combined with the intravenous injection necessary for administering general anaesthesia.

Study objective

1. Show that Growing Up Milk, as part of a healthy diet, can fill nutritional gaps, with special attention to the iron and Vitamin D levels, in young children is more efficient than a healthy diet with cow's milk;

2. Increase of the serum iron and vitamin D status in the subjects receiving the study product (GUM) in comparison the subjects receiving control product.

Study design

Time points of the outcome V0 (screening); V1 (week 10); V2 (week 20).

In between the visits telephone calls to check the general status.

Intervention

Duration of intervention: 20 weeks;

Intervention group: low energy Growing up Milk;

Control group: Cows Milk.
Both products will be taken in amounts of 300-500 ml/day. Both products will be available as a powder.

Contacts

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Eligibility criteria

Inclusion criteria

1. Apparently healthy male and female subjects between 12 and 36 months of age;

2. Stable health status (i.e. being unknown with chronic or recent acute diseases) and expected to remain stable;

3. Familiar with and currently drinking milk products; expected study product intake of 300-500 ml per day;

4. Written informed consent from parents.

Exclusion criteria

1. Known infection during the last week or infection needing medical assistance or treatment during the last 2 weeks;

2. Any case of anaemia treated with pharmaceutical product in the last three months;

3. Any relevant congenital abnormality, chromosomal disorder or severe disease (such as tracheoesophageal fistula, tracheomalacia, major congenital heart disease, Down’s syndrome, HIV, cancer);

4. Disorders requiring a special diet (such as food intolerance or food allergy or complaints such as reflux, constipation and cramps for which special toddler formula is required);

5. Current use of anti-regurgitation, anti-reflux or laxative medication;

6. Known hemoglobinopathies or thalassaemia;

7. Blood transfusion received within the last 6 months;

8. Investigator’s uncertainty about the willingness or ability of the parents to comply with the protocol requirements;

9. Participation in any other study involving investigational or marketed products concomitantly or within 2 weeks prior to entering the study;

10. Expected or foreseen inability of the subject and/or their families to adhere to protocol instructions, including daily completion of the diary by the parents;

11. Known allergy or intolerance to components of the investigational and/or control study product, eg. milk powder, lactose or fish protein;

12. Vaccination with a live or live-attenuated vaccine received during the last two weeks.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012
Enrollment:	288
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2012
Application type:	First submission

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
NTR-new	NL3457
NTR-old	NTR3609
Other	Danone Research : Tod.1.C/L/0
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A