

The effect of isomaltulose enriched and mineral and vitamin fortified growing-up milk on cognitive performance in young children (5-6 years old).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25200

Source

NTR

Health condition

memory, attention span.

Sponsors and support

Primary sponsor: Fakultas Kedokteran Universitas Indonesia
Dept of Child Health Medical School
Jl Salemba Raya 6
Jakarta Pusat
Indonesia

Source(s) of monetary or material Support: FrieslandCampina
P. Stuyvesantweg 1
8937 AC Leeuwarden
The Netherlands

Intervention

Outcome measures

Primary outcome

Scores on memory and attention span during the first 180 minutes following the consumption of the test product.

Secondary outcome

Other markers of cognitive performance that come from the use of the UBC test battery.

Study description

Background summary

There is much evidence to support positive effects of breakfast on cognitive performance of children. So far this is especially related to the glycemic index of the meals, the carbohydrates in particular. This study intends to show the particular acute effect of two doses of isomaltulose (5 and 2.5 g per serving), with a glycemic index of 32, as added to minerals and vitamins enriched growing up milk on cognitive performance (working memory and attention span in particular). The study will be performed in Indonesian children aged 5-6 years recruited in Jakarta.

Study objective

Isomaltulose reduces the decline in working memory and attention span in older children.

This reduction in decline is also seen when lower amounts of isomaltulose are combined with a mix of minerals and vitamins.

Study design

Cognitive performance tests will be done at baseline and 60, 120 and 180 minutes postdose. Cognitive performance tests will be done on the last day of the intervention period.

The cognitive performance is measured by the CDR System, a cognitive performance test battery, from United Biosource Corporation, Wayne, USA.

Intervention

1. A: Regular Growing up milk (GUM);
2. B: A + Isomaltulose;
3. C: A + Isomaltulose and lowered protein;
4. D: A + Isomaltulose (half the dose of B) + mix of vitamins and minerals.

Each test product will be consumed for 14 days.

Contacts

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Eligibility criteria

Inclusion criteria

1. Normal score on Wechsler Scales;
2. Hb within the normal range;
3. Average height;
4. Normal body weight;
5. Normal dietary pattern (food questionnaire);

6. Regular and easy milk consumption (2*200 ml per day).

Exclusion criteria

Symptoms of or diagnosed for allergy, chronic infections, thyroid disorders, diabetes or lactose intolerance, and mental disturbances or retarded development.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	04-05-2010
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	NL2189
NTR-old	NTR2313
Other	FrieslandCampina Innovation International : Nutr-AS-002-2010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A