

The influence of a dietary advice on subclinical hypothyroidism in children, a randomised controlled trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20840

Source

NTR

Health condition

children with subclinical hypothyroidism

Sponsors and support

Primary sponsor: Ziekenhuis Groep Twente

Medisch spectrum Twente

Source(s) of monetary or material Support: initiator=sponsor

Intervention

Outcome measures

Primary outcome

TSH levels

Secondary outcome

- Influence the tiredness

- decrease the anti-TPO
- influence the body mass index (BMI)
- influence the lipid profile

Study description

Background summary

Rationale: Subclinical hypothyroidism is a common disorder in early childhood. At the moment there is no suitable therapy. However, several studies claim subclinical hypothyroidism can have serious consequences. At first it can progress to overt hypothyroidism, but secondly and probably more important, it is associated with metabolic syndrome, increased cardiovascular risk, and increased risk of depression, anxiety and panic attacks in adulthood. Recent studies suggest a beneficial effect of dietary advice consisting of green vegetables, beef and whole dairy products on the TSH-level. This is important, because in this way prevention of development of metabolic syndrome and other complications can be achieved. There are no randomised controlled trials that have investigated the effects of a dietary change in children. The only known RCT's have been performed in adult populations.

Study population: Children aged 1-18 years with a diagnosis of subclinical hypothyroidism (TSH > 4,2 mU/l and normal FT4 values).

Main study parameters/endpoints: The main study parameter is the TSH-level. Secondary endpoints are lipid profile, BMI and tiredness.

Study objective

To evaluate whether a dietary advice of green vegetables, beef and whole dairy products during six months including standard supportive care can decrease the TSH-level compared to standard supportive care alone in children aged 1-18 years with subclinical hypothyroidism.

Study design

t=0, 3 months and 6 months

Intervention

The investigational product is a nutrient rich dietary advice consisting of green vegetables, beef and whole dairy products.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age is 1-18 years
2. Diagnosis of subclinical hypothyroidism by pediatrician
3. Understanding of Dutch language by parents

Exclusion criteria

1. Clinical hypothyroidism (FT4 < 10pmol/L)
2. Treatment with levothyroxine
3. Immunological deficiencies
4. Cow's milk allergy
5. Known or suspected disorder of intestinal absorption (e.g. celiac disease)

6. Disorders requiring a special diet

7. Any relevant congenital abnormality, anatomical abnormality, chromosomal disorder or severe disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2015
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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	NL4891
NTR-old	NTR5138
Other	ABR-nummer : 52712 / NL 52712.044.15

Study results

Summary results

<http://www.scirp.org/journal/Articles.aspx?searchCode=gaag&searchField=All&page=1>