The influence of a dietary advice consisting of green vegetables, beef and whole dairy products on subclinical hypothyroidism in children, a randomised controlled trial

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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 1-12 years with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON47234

Source
ToetsingOnline

Brief title
Influence of a dietary advice on subclinical hypothyroidism in children

Condition

- Thyroid gland disorders

Synonym
impaired thyroid function, Subclinical hypothyroidism

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: Children, Dietary Advice, Subclinical hypothyroidism

Outcome measures

Primary outcome

The main study parameters are (measured with venapunction at 0,3 and 6 months):

- TSH-level (measurement with electro-chemiluminescence sandwich immunoassay on

a COBAS 6000 (Roche Diagnostics)).

Secondary outcome

- Anti-TPO (venapunction at 0 and 6 months)

- Length and weight (at 0, 3 and 6 months)

- Tiredness questionnaire, age-dependent for 2-4y, 5-7y, 8-12y and 13-18y

(recorded by Pediatric QoL Multidimensional Fatigue Scale, Mapi Research Trust)

- Lipid profile (which includes; Total cholesterol, HDL, LDL, chol:HDL ratio,

triglycerides) (venapunction at 0, 3 and 6 months).

Other study parameters:

Parents will receive a questionnaire with various baseline characteristics

(e.g. ethnicity, social environment, gestational age, birth weight)

Study description

Background summary

Subclinical hypothyroidism is a common disorder in 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 en probably more important, it is associated with metabolic syndrome, an increased cardiovascular risk, an elevated cholesterol and triglycerides, and an 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 the metabolic syndrome and other complications can be achieved. There are no randomised controlled trials that investigated the effects of this treatment in children. The only known RCT*s are performed in adult populations.

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 1-12 years with subclinical hypothyroidism. Secondary goals are to assess whether treatment with the dietary advice and standard supportive care compared to standard supportive care alone will influence anti-TPO levels, the lipid profile and the body mass index.

Study design

A multicentre randomised controlled trial will be performed, with an intervention group receiving standard supportive care plus the dietary advice and a control group receiving standard supportive care alone

Intervention

5 times a week green vegetables, 3 times a week beef, >300 mL whole milk a day, whole butter on bread every day. Portion sizes are age appropriate.

Study burden and risks

Participation in the study is risk-free. A non-complex dietary advice as treatment to alleviate the burden of children and parents regarding subclinical hypothyroidism, a second venapunction and a small time investment for the extra follow-up consult are regarded as mild burden of participation. The first and second consult are part of the standard care, the third consult is an extra follow up consult on behalf of the study. The peak incidence of subclinical hypothyroidism is in early childhood and in teenagers and this state can have serious early and late consequences, justifying the choice of treatment group aged 1-12 years.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Age 1-12 years
2. Diagnosis of subclinical hypothyroidism by paediatrician
3. Understanding of Dutch language by parents.

Exclusion criteria

1. Clinical hypothyroidism (FT4 < 10pmol/L)
2. Treatment with levothyroxine
3. Immunological deficiencies
4. Obesity (BMI > 25)
5. Diabetes Mellitus type 1
6. Cow*s milk allergy.

7. Known or suspected disorder of intestinal absorption (e.g. celiac disease).
8. Disorders requiring a special diet.
9. 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)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2015
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	31-07-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
CCMO	NL52712.044.15
Other	NTR volgt