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

Gepubliceerd: 25-03-2015 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20840

Bron
Nationaal Trial Register

Aandoening

children with subclinical hypothyroidism

Ondersteuning

Primaire sponsor: Ziekenhuis Groep Twente
Medisch spectrum Twente
Overige ondersteuning: initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

TSH levels

Toelichting onderzoek

Achtergrond van het onderzoek

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 en 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.

Doel van het onderzoek

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.

Onderzoeksopzet

t=0, 3 months and 6 months

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Ziekenhuis Groep Twente

van der Gaag
Geerdinksweg 141

Hengelo
The Netherlands

Wetenschappelijk

Ziekenhuis Groep Twente

van der Gaag
Geerdinksweg 141

Hengelo
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age is 1-18 years

2. Diagnosis of subclinical hypothyroidism by pediatrician

3. Understanding of Dutch language by parents

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2015
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4891
NTR-old	NTR5138
Ander register	ABR-nummer : 52712 / NL 52712.044.15

Resultaten

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