Subclinical Hyperthyroidism "To Treat or Not to Treat?" A Dutch Multicenter Trial.

Gepubliceerd: 21-06-2005 Laatst bijgewerkt: 13-12-2022

To provide evidence that restoration of euthyroidism (normal TSH) improves thyrotoxic symptoms and signs and quality of life and lowers the risk of subsequent atrial fibrillation and bone loss in subjects with endogenous subclinical hyperthyroidism.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21676

Bron
NTR

Verkorte titel
SUBstudy / SUBstudie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Progression to overt hyperthyroidism: TSH, fT4, T3 every year;
2. Changes in (thyrotoxic) symptoms (null-hypothesis: radioiodine does not cause improvement):
2.1 Quality of life – short form 36 Health Survey: on T=0, T=2 and T=5 years;
2.2 Modified hyperthyroid symptom scale: on T=0, T=2 and T=5 years;
2.3 In the treatment group on T= 1 year: duration of admission to hospital for administration of I131 (if necessary) and signs or symptoms of iodine induced thyroiditis or Graves like disease following iodine treatment making medical treatment necessary;
3. Cardiac changes (null-hypothesis: radioiodine does not prevent development of atrial fibrillation):

3.1 12-lead ECG: on T=0, T=2 and T=5 years;
3.2 Holter monitoring (24 hour): mean 24-hour heart rate, number of PAC and VES: on T=0, T=2 and T=5 years;
4. Changes in bone mineral density (null-hypothesis: radioiodine does not prevent deterioration of BMD): DEXA (Hologic or Lunar) L1-L4 and (right) femoral neck): on T=0, T=2 and T=5 years.

Toelichting onderzoek

Achtergrond van het onderzoek

In various major hospitals, both academic as well as peripheral medical centers, patients fulfilling the inclusion criteria will be selected. Participants with subclinical hyperthyroidism will be randomised into two groups. The first group will be treated for subclinical hyperthyroidism by 131I. The second group will not undergo treatment.
A central randomization procedure (by fax or via website) taking into account sex and age will be performed (12 strata).

Doel van het onderzoek

To provide evidence that restoration of euthyroidism (normal TSH) improves thyrotoxic symptoms and signs and quality of life and lowers the risk of subsequent atrial fibrillation and bone loss in subjects with endogenous subclinical hyperthyroidism.

Onderzoeksproduct en/of interventie

Randomized clinical trial comparing active treatment with 131I with no treatment in subjects with endogenous subclinical hyperthyroidism in a multicenter study.

Contactpersonen

Publiek

Univerity Medical Center St Radboud, Department of Endocrinologie, huispost 531,
P.O. Box 9101
E.H. Hoogendoorn
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3614599

Wetenschappelijk

Univerity Medical Center St Radboud, Department of Endocrinologie, huispost 531,
P.O. Box 9101
E.H. Hoogendoorn
Nijmegen 6500 HB
The Netherlands
+31 (0)24 3614599

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subclinical hyperthyroidism [TSH <= 0.1 mU/L, fT4 and T3 within the normal range of the own laboratory (determined 2 times in own laboratory with an interval of at least 2 months];

2. Endogenous cause of subclinical hyperthyroidism limited to autonomous adenoma or multinodular goiter (diagnosis made by the attending physician, based on palpation and the result of a thyroid scintigram);

3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medication with anti-thyroid drugs in the last 3 months (also not allowed during follow-up), thyroid hormone in the last 3 months (allowed during follow-up, but TSH levels should be kept between 0.1 mU/L and the upper limit of normal in the own laboratory) and oral glucocorticoids in the last 3 months (allowed during follow-up when absolutely necessary, but patients in whom glucocorticoids are started cannot be evaluated with respect to changes in BMD);

2. Radioiodine therapy in the past;

3. Iodine-induced subclinical hyperthyroidism;

4. Pituitary or hypothalamic insufficiency;

5. Pregnancy;

6. Age <= 50 years and >80 years;

7. Severe non-thyroidal illness;

8. Drug abuse;

9. Unstable angina pectoris, (history of) atrial fibrillation, (history of) congestive heart failure;

10. (History of) osteoporotic fracture(s);

11. Patients younger than 70 years of age with a bone mineral density T-score <–2.5 SD, or older than 70 years of age with a bone mineral density Z-score <1.0 SD;

12. These patients can be randomized but in case it is decided to treat them with antiosteoporotic drugs they cannot be evaluated with respect to changes in BMD;

13. Use of betablockers in the last three months. These patients can be randomised but cannot be evaluated with respect to
general and cardiac symptoms. The same applies to patients in whom betablokkers are started during follow up;

14. Other symptoms or signs of hyperthyroidism or obstruction of vital structures which in the opinion of the attending physician urge to active treatment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2003
Aantal proefpersonen:	192
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-06-2005
Soort:	Eerste indiening

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	NL52
NTR-old	NTR75
Ander register	: N/A
ISRCTN	ISRCTN04337637

Resultaten

Samenvatting resultaten
N/A