

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21676

### Source

NTR

### Brief title

SUBstudy / SUBstudie

### Intervention

### Outcome measures

#### Primary outcome

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.

## **Secondary outcome**

1. Progression to overt hyperthyroidism: TSH, fT4, T3 every year.

2. Changes in (thyrotoxic) symptoms (null-hypothesis: radioiodine does not cause improvement):

a. Quality of life – short form 36 Health Survey: on T=0, T=2 and T=5 years;

b. Modified hyperthyroid symptom scale: on T=0, T=2 and T=5 years;

c. 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):

a. 12-lead ECG: on T=0, T=2 and T=5 years;

b. 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.

## **Study description**

### **Background summary**

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 <sup>131</sup>I. 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).

### **Study objective**

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.

## **Intervention**

Randomized clinical trial comparing active treatment with  $^{131}\text{I}$  with no treatment in subjects with endogenous subclinical hyperthyroidism in a multicenter study.

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

1. Subclinical hyperthyroidism [ $\text{TSH} \leq 0.1 \text{ mU/L}$ ,  $\text{fT}_4$  and  $\text{T}_3$  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.

## Exclusion criteria

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  $\leq 50$  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.

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2003
Enrollment:	192
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	21-06-2005
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	NL52
NTR-old	NTR75

**Register**

Other  
ISRCTN

**ID**

: N/A  
ISRCTN04337637

## Study results

**Summary results**

N/A