# Effect of L-thyroxine on progression of Carotid Atherosclerosis in Subclinical Hypothyroidism

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
21/05/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/05/2008	Completed	Results
Last Edited	Condition category	Individual participant data
04/03/2009	Circulatory System	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MCT-79197

# Study information

#### Scientific Title

Effect of L-thyroxine on progression of Carotid Atherosclerosis in Subclinical Hypothyroidism: a single centre, randomised, two-arm parallel, placebo-controlled drug intervention

#### **Acronym**

T4CASH

#### **Study objectives**

Primary hypothesis:

That treatment of patients with subclinical hypothyroidism with L-thyroxine to achieve a target thyroid stimulating hormone (TSH) less than 2 and greater than 0.4 mIU/L and free thyroxine (FT4) greater than 4 and less than 25 pmol/L, will slow progression of carotid plaque volume and carotid intima-media thickness (IMT), compared to placebo.

#### Secondary hypotheses:

That treatment with L-thyroxine will improve control of plasma lipids and homocysteine, and reduce levels of C-reactive protein, weight, waist circumference and insulin resistance.

Please note that as of 04/03/2009 the anticipated end date in this record was amended; the previous date at the time of registration was:

Initial anticipated end date: 31/07/2007

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

Research Ethics Board of the University of Western Ontario gave approval on the 24th June 2004 (ref: 10458).

# Study design

Single centre, randomised, double blind (participant, investigator, caregiver, outcome assessor and data analyst), two-arm parallel, placebo-controlled drug intervention

# Primary study design

Interventional

### Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

Health condition(s) or problem(s) studied

#### Atherosclerosis, subclinical hypothyroidism

#### **Interventions**

1. L-thyroxine, beginning at 0.0125 and gradually increased to achieve target TSH level greater than 0.4 and less than 2 and FT4 greater than 4 and less than 25 pmol/L for 18 months

2. Matching placebo, with dummy dose adjustments for 18 months

#### Contact for public queries:

Tisha Mabb

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#### Intervention Type

Drug

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

L-thyroxine

#### Primary outcome measure

Rate of progression of carotid plaque volume (mm<sup>3</sup>) measured by 3-D ultrasound at baseline and 18 months.

#### Secondary outcome measures

- 1. Intima-media thickness (IMT), measured at baseline and 18 months
- 2. Weight, waist circumference, measured every 6 months
- 3. Insulin resistance by Homeostasis Model Assessment (HOMA), homocysteine, lipids, measured at baseline and 19 months

#### Overall study start date

01/07/2006

#### Completion date

31/07/2010

# **Eligibility**

#### Key inclusion criteria

Male or female patients:

1. With subclinical hypothyroidism, defined as a TSH of 3 to 10 mU/L, and a normal serum free thyroxine level (FT4 11 to 25 pmol/L), and

- 2. Measurable plaque in the carotid arteries
- 3. Aged greater than or equal to 45 years

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

# Target number of participants

254

#### Key exclusion criteria

- 1. Unwilling to give informed consent
- 2. History of atrial fibrillation
- 3. Unstable angina, or angina requiring nitroglycerine as often as once a month
- 4. Unlikely to adhere to the protocol
- 5. Unlikely to survive 18 months because of severe illness such as cancer
- 6. At risk of pregnancy

#### Date of first enrolment

01/07/2006

#### Date of final enrolment

31/07/2010

# Locations

#### Countries of recruitment

Canada

# Study participating centre Stroke Prevention & Atherosclerosis Research Centre (SPARC)

London, Ontario Canada N6G 2V2

# Sponsor information

#### Organisation

Robarts Research Institute (Canada)

#### Sponsor details

P.O. Box 5015 100 Perth Drive London, Ontario Canada N6A 5K8 +1 519 663 5777 lchapman@robarts.ca

#### Sponsor type

Research organisation

#### Website

http://www.robarts.ca/home.php

#### ROR

https://ror.org/01e36dv41

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-79197)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration