

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr John David Spence

Contact details
Stroke Prevention & Atherosclerosis Research Centre (SPARC)
Robarts Research Institute
Siebens-Drake Research Bldg.
1400 Western Rd
London, Ontario
Canada
N6G 2V2
+1 519 663 3113
dspence@robarts.ca

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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

Lab Manager

Stroke Prevention & Atherosclerosis Research Centre (SPARC)

Robarts Research Institute
Siebens-Drake Research Bldg.
1400 Western Rd
London, Ontario
N6G 2V2
Canada
Email: tisha@robarts.ca

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

L-thyroxine

Primary outcome(s)

Rate of progression of carotid plaque volume (mm³) measured by 3-D ultrasound at baseline and 18 months.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration