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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/05/2008	**Overall study status** Completed	
Last Edited 04/03/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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).

Primary study design
Interventional

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

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:
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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
L-thyroxine

Primary outcome(s)
Rate of progression of carotid plaque volume (mm^3) 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