

BEISPIELSTUDIE

Multi-modal effects of thyroid hormone replacement for untreated older adults with subclinical hypothyroidism: a randomised placebo-controlled trial

KATEGORISIERUNG

Gattung

Forschungsprojekt mit lebenden Personen

Art

Unterart

Klinischer Versuch mit Arzneimitteln (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g MepV)

BACKGROUND

Subclinical hypothyroidism is a common condition (81,8%) among older men and women. Thyroid hormone affects many physiological systems, including the vascular tree, heart, skeletal muscle, and brain. Thyroxin is substituted to overcome thyroid hormone deficiency, and may offer multisystem benefits to older people with subclinical hypothyroidism. This multicentre randomised placebo controlled trial aimed to assess the effects of thyroxin replacement in older adults who have persistent subclinical hypothyroidism.

METHODS

Men aged ≥ 65 years, who suffered from subclinical hypothyroidism, were randomized to either a thyroxin (Eltroxin-LF®) starting dose of 50 g daily p.o. (reduced to 25 g daily in subjects < 50 kg body weight, or if known coronary heart disease) or a matching placebo p.o. Eltroxin-LF®. (The manufacturer of Eltroxin-LF® provided placebo tablets that looked identical.) Subjects were reviewed face-to-face by study nurses at recruitment, study baseline, 6-8 weeks after baseline, after each dose change, 12 months, and annually thereafter. Study nurses made interim telephone contact at 6, 18, 30, and 42 months; possible cardiovascular and serious adverse events were recorded. The primary outcome included fatal and non-fatal cardiovascular events (fatal and non-fatal acute myocardial infarction and stroke; amputations for peripheral vascular disease; revascularisations for atherosclerotic vascular disease, including for acute coronary syndrome; heart failure hospitalisations).

CATEGORISER-FRAGEN

Fällt das Forschungsprojekt in den Geltungsbereich des Humanforschungsgesetzes?

Ja

BECAUSE

This project was based on a study protocol that defines the exact procedures to be used. It included a relatively large number of persons and was not based on individual cases ("method-driven search for generalizable knowledge", defined as research by HRA). Men ("persons") aged ≥ 65 years, who suffered from untreated subclinical hypothyroidism ("research concerning human diseases"), were treated either with thyroxin hormone substitution (Eltroxin-LF®) or placebo.

Handelt es sich bei dem Forschungsprojekt um ein Projekt mit lebenden Personen?

Ja

BECAUSE

Men ("persons") aged ≥ 65 years, who suffered from subclinical hypothyroidism were included in this research project.

Handelt es sich bei dem Forschungsprojekt um einen klinischen Versuch im Sinne der KlinV oder der KlinV-Mep?

Ja

BECAUSE

The investigator randomly allocated ("prospectively assigned") men ("persons") who suffered from subclinical hypothyroidism to receive either thyroxin (Eltroxin-LF®) or placebo ("health-related intervention (therapeutic measure)"). The purpose of the study was to compare the number of fatal and non-fatal cardiovascular events ("to investigate its effect on health").

Wird in der Studie ein Arzneimittel (einschliesslich Kombinationen nach Art. 2 Abs. 1 Bst. f und g Medizinprodukteverordnung (MepV) vom 1. Juli 2020) untersucht?

Ja

BECAUSE

The effects of thyroxin (Eltroxin-LF®) and placebo were investigated ("medicinal products") in this clinical trial.

Wird in der Studie ein Medizinprodukt (In-vitro-Diagnostika ausgenommen) oder ein anderes Produkt nach Artikel 1 der Medizinprodukteverordnung (MepV) (Stand am 26. Mai 2022) untersucht?

Nein

BECAUSE

Wird in der Studie eine Intervention untersucht, die weder ein Heilmittel oder ein Transplantatprodukt, noch ein Produkt nach Art. 2a Abs. 2 Heilmittelgesetz (HMG) (Stand ab 26. Mai 2021) oder eine Transplantation ist?

Nein

BECAUSE

Wird in der Studie eine Gentherapie oder ein pathogener Organismus untersucht?

Nein

BECAUSE

Ist das Arzneimittel in der Schweiz zugelassen?

Ja

BECAUSE

The effects of thyroxin (Eltroxin-LF®) and placebo were investigated in this clinical trial. Eltroxin-LF® is "authorised" for the Swiss market (approval number: 29812 (Swissmedic)). The placebo was manufactured specifically for this research project. Aspects related to good manufacturing practice need to be checked by Swissmedic.

Wird in der Studie ein Placebo verwendet oder wird der Originalzustand des verwendeten Arzneimittels oder seine Verpackung verändert?

Ja

BECAUSE

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