# Absorption of levothyroxine with breakfast in healthy women

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
23/01/2015	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
30/01/2015	Completed	Results
Last Edited	Condition category	Individual participant data
26/01/2017	Other	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Background and study aims

Levothyroxine is a synthetic thyroid hormone that is normally used to substitute the natural hormone when the thyroid, for several reasons, does not produce this hormone at all or does not produce it in sufficient amounts. The absorption of levothyroxine is affected by the intake of food and the recommendation is to take it in the fasting state and wait between 30 min and 1 hour before having breakfast. Exactly how long one should wait before the meal and whether different formulations require different fasting times have not been investigated. The aim in this study is to compare the absorption profile of oral levothyroxine administered at a single dose in healthy volunteers at different times before breakfast.

Who can participate?

Women, aged 18–50 years old, who are generally healthy

What does the study involve?

Healthy volunteers will be randomly allocated to oral levothyroxine as a single dose (600 µg) at different times: they will take two or three single doses of levothyroxine in the fasting state or 15 minutes and/or 30 minutes before a light breakfast.

What are the possible benefits and risks of participating?

Levothyroxine is usually well tolerated, although, in the event of hyperdosing, symptoms may occur such as palpitations, alterations of the cardiac rhythm, increased heart rate frequency, muscular cramps, insomnia, diarrhoea, vomiting, nervousness, headache, sweating, weight decrease, tremors, alterations of the menstrual cycle or loss of hair. There are no direct benefits from the participation.

Where is the study run from? Cross Research SA (Switzerland)

When is the study starting and how long is it expected to run for? From January 2015 to September 2015

Who is funding the study?
IBSA Institut Biochimique SA (Switzerland)

Who is the main contact? Mrs Claudia Scarsi

## Contact information

#### Type(s)

Scientific

#### Contact name

Mrs Claudia Scarsi

#### Contact details

Via del Piano Pambio-Noranco Switzerland 6915

# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

14CH/T412

# Study information

#### Scientific Title

Effect of food on levothyroxine absorption following a single oral dose of 600  $\mu$ g in healthy women: an randomised open-label pilot study

## **Study objectives**

To verifiy the absorption of levothyroxine after meals.

On 30/06/2015 the following changes were made to the trial record:

- 1. The overall trial end date was changed from 30/05/2015 to 30/09/2015.
- 2. The target number of participants was changed from 30 to 40.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Comitato Etico Cantonale (Switzerland), 20/01/2015 (amendment n. 2 21/04/2015), reference number: 2871

#### Study design

Randomised open-label three-way bioavailability pilot study in two parts

#### Primary study design

Interventional

#### Secondary study design

Randomised parallel trial

#### Study setting(s)

Other

#### Study type(s)

Other

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Oral levothyroxine

#### Interventions

Healthy volunteers were administered oral levothyroxine as a single dose (600 mcg):

- 1. In the fasting state
- 2. 15 minutes before a light breakfast
- 3. 30 minutes before a light breakfast

#### Intervention Type

Drug

#### Phase

Not Applicable

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

Levothyroxine

#### Primary outcome measure

Effect of food on levothyroxine sodium bioavailability by comparison of the rate (Cmax) and extent (AUC0-t) of absorption of serum levothyroxine after a single dose of 600 µg: measured over 24 hours after each single dose, by repeated blood sampling and analytical quantitation of the serum concentration of levothyroxine

#### Secondary outcome measures

Effect of food on the secondary levothyroxine pharmacokinetic parameters after a single dose of 600 µg: measured over 24 hours after each single dose, by repeated blood sampling and analytical quantitation of the serum concentration of levothyroxine

## Overall study start date

28/11/2014

## Completion date

# **Eligibility**

#### Key inclusion criteria

- 1. Signed written informed consent before inclusion in the study
- 2. Age 18-50 years old
- 3. Body-mass index: 18.5–27 kg/m2
- 4. Vital signs: systolic blood pressure 100–139 mmHg, diastolic blood pressure 50–89 mmHg, heart rate 50–90 beats per minute, measured after 5 minutes at rest in the sitting position
- 5. Ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and comply with the requirements of the entire study
- 6. Women of child-bearing potential must be using at least one of the following reliable methods of contraception and must continue up to 30 days after the last investigational medicinal product administration: 6.1. Hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit
- 6.2. Non-hormonal intrauterine device or female condom with spermicide or contraceptive sponge with spermicide or diaphragm with spermicide or cervical cap with spermicide for at least 2 months before the screening visit
- 6.3. Male sexual partner who agrees to use a male condom with spermicide
- 6.4. Sterile sexual partner
- 6.5. Non-child-bearing potential or in post-menopausal status for at least 1 year
- 7. All thyroid function tests within normal limits

#### Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

**Female** 

#### Target number of participants

40

#### Kev exclusion criteria

- 1. Electrocardiogram 12-leads (supine position): clinically significant abnormalities
- 2. Physical findings: clinically significant abnormal physical findings that could interfere with the objectives of the study
- 3. Laboratory analyses: clinically significant abnormal laboratory values indicative of physical illness
- 4. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the investigator considers may affect the outcome of the study
- 5. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular (including active arrhythmia or history of arrhythmia, particularly atrial fibrillation), respiratory, skin,

haematological, genitourinary or neurological diseases that may interfere with the aim of the study; history of endocrine abnormalities, particularly thyroid, hypophysis and hypothalamus dysfunction; autoimmune diseases such as Basedow-Graves and Hashimoto morbi; neoplasia 6. Medications, including over the counter drugs and herbal remedies for 2 weeks before the start of the study

- 7. Investigative drug studies: participation in the evaluation of any investigational product for 3 months before this study; the 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study
- 8. Blood donations for 3 months before this study
- 9. Drug, alcohol, caffeine, tobacco: history of drug, alcohol (more than one drink per day defined according to the USDA Dietary Guidelines 2010), caffeine (more than five cups of coffee or tea per day) or tobacco abuse (at least 10 cigarettes per day)
- 10. Positive drug test results at screening or day-1
- 11. Positive alcohol breath test at day -1
- 12. Abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before this study
- 13. Vegetarians
- 14. Positive or missing pregnancy test at screening or day-1
- 15. Pregnant or lactating women

Date of first enrolment 26/01/2015

**Date of final enrolment** 09/06/2015

## Locations

**Countries of recruitment** Switzerland

Study participating centre Cross Research SA Switzerland 6894

# Sponsor information

**Organisation**IBSA Institut Biochimique SA

Sponsor details

Via del Piano Pambio-Noranco Switzerland 6915

#### Sponsor type

Industry

#### **ROR**

https://ror.org/051tj3a26

# Funder(s)

#### Funder type

Industry

#### Funder Name

IBSA Institut Biochimique SA (Switzerland)

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

## Intention to publish date

08/11/2018

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Claudia Scarsi (Claudia.scarsi@ibsa.ch)

## IPD sharing plan summary

Available on request