# Levothyroxine treatment during Ramadan

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
13/02/2021		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/02/2021	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
22/08/2022	Nutritional Metabolic Endocrine			

### Plain English summary of protocol

Background and study aims

Hypothyroidism occurs when the body doesn't produce enough thyroid hormones. The researchers have previously shown that plasma (blood) thyroid-stimulating hormone (TSH) rises significantly after Ramadan in levothyroxine-treated hypothyroid patients, possibly as a result of lifestyle alterations and time restrictions during the non-fasting period from dusk until dawn. The aim of this study is to determine the best time to take levothyroxine during Ramadan so as to minimize changes in thyroid function tests during this period.

### Who can participate?

Patients aged 18 or over with an underactive thyroid gland (hypothyroidism) who have been on thyroid hormone replacement therapy (levothyroxine) for 6 or more months and are planning to fast during Ramadan 2019

## What does the study involve?

Participants are randomly allocated to take levothyroxine at one of the following three times during Ramadan: (group 1) at dusk 30 minutes before Iftar meal, (group 2) 3 or more hours after Iftar meal, or (group 3) at dawn 30 minutes before Suhur meal. Thyroid function tests are performed within 3 months before Ramadan and within 6-weeks after Ramadan.

What are the possible benefits and risks of participating? There are no anticipated benefits or risks for participation in this study.

Where is the study run from?
Cleveland Clinic Abu Dhabi (United Arab Emirates)

When is the study starting and how long is it expected to run for? March 2018 to July 2019

Who is funding the study?

- 1. Investigator initiated and funded
- 2. Roche Diagnostics provided test kits for plasma TSH and Free-T4

Who is the main contact?
Dr Samer El-Kaissi
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## Contact information

## Type(s)

Scientific

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## Type(s)

Public

#### Contact name

Dr Samer El-Kaissi

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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

Nil known

## Study information

Scientific Title

Levothyroxine treatment during Ramadan: a prospective study

#### Acronym

Levo-Ramadan

## Study objectives

This study aims to determine the best time for taking levothyroxine during Ramadan so as to minimize changes in thyroid function tests during this period.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 17/04/2019, Cleveland Clinic Abu Dhabi Research Ethics Committee (Cleveland Clinic Abu Dhabi, PO Box 112412, Abu Dhabi, UAE; +971 (0)2 501 9000; REC@clevelandclinicabudhabi. ae), ref: A2019-023

#### Study design

Single-center interventional prospective randomized trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

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

Hypothyroid is m

#### **Interventions**

In a randomized prospective design, hypothyroid patients taking levothyroxine are randomized to take levothyroxine at one of the following three times during Ramadan: (group 1) at dusk 30 minutes before Iftar meal, (group 2) 3 or more hours after Iftar meal, or (group 3) at dawn 30 minutes before Suhur meal. For groups (2) and (3), patients are instructed to allow a minimum of 3 hours between the last meal and levothyroxine and to refrain from eating and drinking for at least 30 minutes after taking levothyroxine. Levothyroxine administration instructions are provided verbally by telephone and a text message is sent to all patients midway through Ramadan as a reminder to adhere to the instructions.

## Intervention Type

Drug

#### Phase

Not Applicable

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

Levothyroxine

### Primary outcome(s)

Thyroid function tests (plasma TSH and free-T4) measured on the Roche e601 immunoassay analyzer using the electrochemiluminescence immunoassay (ECLIA) sandwich principle for TSH

and the ECLIA competition principle for free-T4, within 3 months before Ramadan and repeated within 6 weeks post-Ramadan

### Key secondary outcome(s))

- 1. The impact of age and gender on the primary outcome measure, change in thyroid function tests (see above) from pre-to post-Ramadan
- 2. Patient compliance and satisfaction with the assigned randomized treatment assessed with a telephone call to each patient at the end of the study

### Completion date

15/07/2019

## Eligibility

## Key inclusion criteria

- 1. Age 18 years or older
- 2. Hypothyroidism treated with levothyroxine for over 6 months
- 3. Planning to fast during the month of Ramadan
- 3. Ability to provide informed consent

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### Total final enrolment

148

#### Key exclusion criteria

- 1. Age less than 18 years
- 2. Inability to provide an informed consent

#### Date of first enrolment

23/04/2019

#### Date of final enrolment

04/05/2019

## Locations

#### Countries of recruitment

**United Arab Emirates** 

## Study participating centre Cleveland Clinic Abu Dhabi

Al Maryah Island Abu Dhabi United Arab Emirates AD

# Sponsor information

## Organisation

Cleveland Clinic Abu Dhabi

## Funder(s)

## Funder type

Other

#### Funder Name

Investigator initiated and funded

#### **Funder Name**

**Roche Diagnostics** 

#### Alternative Name(s)

**Roche Diagnostics Corporation** 

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

For-profit companies (industry)

#### Location

United States of America

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. A deidentified dataset will be stored on a password-protected work computer in keeping with REC regulations.

## IPD sharing plan summary

Not expected to be made available

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/08/2021	22/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes