

# Levothyroxine treatment during Ramadan

<b>Submission date</b> 13/02/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/08/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

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## Additional identifiers

## 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**

Hypothyroidism

## **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**

All

**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?
<a href="#">Results article</a>		10/08/2021	22/08/2022	Yes	No