ISRCTN54141719 https://doi.org/10.1186/ISRCTN54141719

Levothyroxine treatment during Ramadan

Submission date
13/02/2021

Recruitment status
No longer recruiting

Registration date
17/02/2021

Overall study status
Completed

Last Edited
22/08/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
elkaiss@clevelandclinicabudhabi.ae

Contact information

Type(s)
Scientific

Contact name
Dr Samer El-Kaissi

Contact details
Cleveland Clinic Abu Dhabi
Abu Dhabi
United Arab Emirates
Abu Dhabi
+971 (0)2 501 9000
elkaiss@clevelandclinicabudhabi.ae

Type(s)
Public

Contact name
Dr Samer El-Kaissi

Contact details
Cleveland Clinic Abu Dhabi
Abu Dhabi
United Arab Emirates
Abu Dhabi
+971 (0)2 501 9000
elkaiss@clevelandclinicabudhabi.ae

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
30/03/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 (50 patients in each arm of the study)

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

Sponsor details
Al Maryah Island
Abu Dhabi
United Arab Emirates
Abu Dhabi
+ 971 (2) 501 9000
REC@clevelandclinicabudhabi.ae

Sponsor type
Hospital/treatment centre

Website
https://www.clevelandclinicabudhabi.ae/en/pages/default.aspx

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal. No additional documents are available.

Intention to publish date
30/06/2021

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