ISRCTN17501072 https://doi.org/10.1186/ISRCTN17501072

Investigation of the use of special camera technology during thyroid surgery to avoid the need for calcium supplementation after surgery

Submission date
12/06/2021

Recruitment status
No longer recruiting

Registration date
24/06/2021

Overall study status
Completed

Last Edited
30/12/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Autofluorescence is the natural emission of light by biological structures. The use of autofluorescence in endocrine surgery is a new, innovative and promising technique that can help the surgeon identify and protect the parathyroid glands during surgery, reducing the likelihood of the need for daily calcium and vitamin D supplements after surgery.
The use of this technology is increasing internationally. Although its safety has been confirmed, there is still not much data on its effectiveness. The aim of this study is to show whether the use of the autofluorescence method reduces the risk of temporary or permanent hypocalcemia (low blood calcium), one of the most serious complications after thyroid surgery.

Who can participate?
Patients aged over 18 years who are scheduled to undergo total thyroidectomy (removal of the thyroid gland), with or without neck lymph node dissection

What does the study involve?
Participants will be randomly allocated to receive thyroid surgery with or without the use of the autofluorescence camera. For the study's validity, the selection of patients must be random and automated by a special algorithm, which means that nor the patient or the doctor will choose if the autofluorescence camera will be used.

What are the possible benefits and risks of participating?
The results of this study will help surgeons internationally to make better use of this new technology. This technique is entirely safe for the patient since it does not require any additional intervention on the patient (surgical or pharmaceutical), the patient does not receive ionizing radiation, it does not endanger their health in any way, and it does not increase surgery time.

Where is the study run from?
Henry Dunant Hospital Center (Greece)

When is the study starting and how long is it expected to run for?
April 2021 to April 2023

Who is funding the study?
Henry Dunant Hospital Center (Greece)

Who is the main contact?
Dr Kyriakos Vamvakidis
info@drvamvakidis.gr

Study website
http://www.parflu.com

Contact information

Type(s)
Scientific

Contact name
Dr Kyriakos Vamvakidis

ORCID ID
https://orcid.org/0000-0002-1663-4839

Contact details
59 Skoufa Street
Athens
Greece
106 72
+30 (0)6944254801
info@drvamvakidis.gr

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
35/26-04-2021

Study information

Scientific Title

Prospective randomized clinical trial for the evaluation of the use of autoFLUorescence technology in the prevention of postoperative hypoPARathyroidism in patients undergoing thyroidectomy with or without neck dissection

Acronym
PARFLU

Study objectives
The use of autofluorescence may assist the surgeon to earlier identify the parathyroid glands during thyroid operations, and as a result, this may reduce the possibility of postoperative temporary or permanent hypoparathyroidism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/06/2021, Board of Ethics of Henry Dunant Hospital Center (107 Mesogeion Ave P. C. 115 26, Athens, Greece; +30 (0)2106979090; g.papazoglou@dunant.gr), ref: none provided

Study design
Single-centre interventional prospective randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Prevention of postoperative hypoparathyroidism in patients undergoing thyroid operations

Interventions
This study will include patients undergoing total thyroidectomy, with or without neck lymph node dissection.

In the first arm, the autofluorescence technique will be used for the intraoperative detection of parathyroid glands.
In the second arm, patients will have a conventional operation.

The allocation of the patients will be random with the use of computer software, neither the patient nor the surgeon will have a choice.

Postoperatively, all patients will have the required blood tests and clinical examination, required to identify those who may develop hyperparathyroidism. The final follow up will take place 6 months after the operation to conclude if the possible postoperative hyperparathyroidism is temporary or permanent.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Autofluorescence system - Viron X Maxer Endoscopy

Primary outcome measure
1. Total calcium levels measured using a blood test (colorimetric method) at baseline, 1 day, 1 week, and 6 months
2. Albumin measured using a blood test (colorimetric method) at baseline, 1 day, 1 week, and 6 months
3. Phosphorous measured using a blood test (colorimetric method) at baseline, 1 day, 1 week, and 6 months
4. Intact parathormone levels measured using a blood test (chemiluminescence immunoassay) at baseline, 1 day, 1 week, and 6 months
5. 25-OH-Vit D measured using a blood test (chemiluminescence immunoassay) at baseline

Secondary outcome measures
1. Number of parathyroid glands detected intraoperatively measured using autofluorescence or direct visualisation during the operation
2. Number of unintentional removals of parathyroid glands measured using the histopathology report at 1 month (after receiving the official report)
3. Number of autotransplantation of parathyroid glands measured using operation notes at day 1

Overall study start date
20/04/2021

Completion date
20/04/2023

Eligibility

Key inclusion criteria
Patients over 18 years old undergoing total thyroidectomy with or without neck lymph node dissection

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Patients undergoing reoperation for thyroid pathology
2. Patients undergoing less than total thyroidectomy (lobectomy, hemithyroidectomy, subtotal thyroidectomy)
3. Patients who have hyperthyroidism
4. Patients who simultaneously with thyroidectomy have an operation for primary, secondary or tertiary hyperparathyroidism

Date of first enrolment
28/06/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Greece

Study participating centre
Henry Dunant Hospital Center
107 Mesogeion Avenue
Athens
Greece
115 26

Sponsor information

Organisation
Henry Dunant Hospital

Sponsor details

107 Mesogeion Avenue
Athens
Greece
115 26
+30 (0)2106972000
endocrinesurgery@dunant.gr

Sponsor type
Hospital/treatment centre

Website
http://www.dunant.gr/default.aspx?id=84&aid=7698&lang=english

ROR
https://ror.org/05n7t4h40

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Henry Dunant Hospital Center

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		30/12/2021	30/12/2021	No	No