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

Submission date	Recruitment status	[X] Prospectively registered		
12/06/2021	No longer recruiting	[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
24/06/2021		Results		
Last Edited		Individual participant data		
30/12/2021	Nutritional, Metabolic, Endocrine	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