

Novel digital multi-modality imaging for the diagnosis of parathyroid adenoma

Submission date 07/03/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/04/2023	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/04/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background study and aims

The main function of the parathyroid glands is to regulate the calcium balance in the body, which is important for processes like nerve and muscle function as well as skeletal structure. Normally, you have four glands, usually located next to the thyroid gland, but it also happens that they can be located somewhere else in the neck or the chest. In parathyroid hyperfunction, one or more parathyroid glands produce too much parathyroid hormone (adenoma), which is something that could lead patients to suffer from kidney, musculoskeletal and heart problems, among others. Previous to treatment, which is usually surgery, localization of the adenoma is usually performed using SPECT (single photon emission computed tomography) and/or contrast-enhanced computed tomography (CT), in two different sessions. Multimodality equipment using SPECT and CT in one session could result in advantages for the patient and the healthcare system. This study aims to evaluate the diagnostic performance of the combination of SPECT and contrast-enhanced 3-phase CT (without contrast and with contrast in arterial and venous phases) for the detection and localization of parathyroid adenoma.

Who can participate?

Adult patients with clinical suspicion of parathyroid adenoma

What does the study involve?

We will perform a contrast-enhanced SPECT-CT in a novel CZT camera

What are the possible benefits and risks of participation?

The expected benefit is the detection, location and anatomical characterization of a suspected parathyroid adenoma. Potential risks would be an adverse reaction to intravenous iodinated contrast.

Where is the study run from?

Clinical Physiology Department, Nuclear Medicine Unit, Linköping University Hospital (Sweden)

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

August 2018 to March 2023

Who is funding the study?

Linköping University Hospital, Clinical Physiology Department and Radiology Department (Sweden)

Who is the main contact?

Miguel Ochoa Figueroa, MD, PhD, miguel.ochoa.figueroa@regionostergotland.se (Sweden)

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Contrast enhanced digital CZT SPECT-CT for the diagnosis of parathyroid adenoma

Study objectives

The use of novel CZT SPECT-CT using intravenous contrast increases the detection rates of parathyroid adenomas.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/03/2019, the Ethics Review Authority in Sweden (Etikprövningsmyndigheten, Box 2110, Uppsala, 750 02, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2019-00501

Study design

Observational study

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Diagnostic

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

Parathyroid adenoma

Interventions

This is a study that included patients with suspected parathyroid adenoma who are referred to our Hospital for an imaging study called parathyroid scintigraphy. We will perform the scintigraphy using a new digital cadmium zinc telluride (CZT) camera which has the ability to acquire 3D images and contrast-enhanced CT at the same time. Both studies are routinely performed in our centre and are well-established studies in these patients worldwide. The approach is to do both at the same time, in order to save time and resources, using a one-stop-shop approach.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Scintigraphy using a digital cadmium zinc telluride (CZT) camera

Primary outcome measure

Accuracy, sensitivity, specificity, positive predictive value and negative predictive value of the test with and without intravenous contrast measured using a digital CZT (cadmium-zinc-telluride) multimodality equipment SPECT-CT (single-photon emission computed tomography-computed tomography) at one timepoint during diagnosis of suspected parathyroid adenoma

Secondary outcome measures

Accuracy, sensitivity, specificity, positive predictive value and negative predictive value of the test of the information provided by a combination of SPECT and CT = contrast-enhanced SPECT-CT, measured using HU (Hounsfield units) of the native, arterial and venous phases in the CT images and the wash-out of the tracer in the SPECT images at one timepoint

Overall study start date

18/08/2018

Completion date

30/06/2023

Eligibility**Key inclusion criteria**

Adult patients referred from the endocrinology department with suspicion of parathyroid adenoma

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

45

Key exclusion criteria

Allergy to iodinated contrast media

Date of first enrolment

09/05/2021

Date of final enrolment

30/03/2023

Locations

Countries of recruitment

Sweden

Study participating centre

Linköping University Hospital

Universitetssjukhuset

Linköping

Sweden

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Sponsor information

Organisation

Linköping University Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.regionostergotland.se/>

ROR

<https://ror.org/05h1aye87>

Funder(s)

Funder type

University/education

Funder Name

Linköpings Universitet

Alternative Name(s)

Linköping University, Linköping University, LiU

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/03/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon reasonable request. Miguel Ochoa Figueroa, MD, PhD. miguel.ochoa.figueroa@regionostergotland.se. Consent from participants was required and obtained. The type of data that can be shared will depend on what is permitted by Swedish law.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			08/03/2023	No	No