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

Submission date 07/03/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/04/2023	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 13/04/2023	**Condition category** Cancer	[_] Individual participant data [_] 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

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Linköping University Hospital

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan			08/03/2023	No	No