ISRCTN23666565 https://doi.org/10.1186/ISRCTN23666565

Does ligation of the thyroid arteries during an operation on the thyroid goiter have an effect on parathyroid function?

Submission date
08/02/2014

Recruitment status
No longer recruiting

Registration date
18/02/2014

Overall study status
Completed

Last Edited
24/07/2020

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
During an operation on the thyroid goitre the arteries for the thyroid gland are usually ligated. The surgeon must see the paratyroid glands. This is the best way to avoid damage to or removal of the parathyroid glands. The ligation of the thyroid arteries and the exposure of the parathyroid glands could have an negative effect on the parathyroid function. The key function of the parathyroid glands is to control the amount of calcium in the blood and within the bones. This study compares two surgery methods and we want to test that the bilateral truncal ligation of the inferior thyroid artery does not alter the parathyroid function.

Who can participate?
Patients who need surgery on the thyroid gland.

What does the study involve?
Patients are randomly allocated to one of two groups. In one group, the inferior thyroid arteries are ligated (this is the method under investigation). In the other group, the inferior thyroid arteries are not ligated (this is the control group). The effect on the parathyroid function is measured. The parathyroid function is measured by blood tests before, during and after the operation. The last test is on day 5 after the operation during the stay in hospital. In addition all patients will receive a clinical examination and will asked about symptoms daily after the operation. The age and how much was resected from the thyroid gland could have an influence on the parathyroid function. This is measured.

What are the possible benefits and risks of participating?
Operations on the thyroid gland present two main risks: damage to the parathyroid glands and injury to a nerve used for the voice. We expect no additional risks.

Where is the study run from?
It is a single center study which takes place in the Departement of Thoracic and Vascular surgery of the SRH Wald-Klinikum Gera, a teachíng hospital of the Friedrich Schiller University of Jena (Germany).

When is the study starting and how long is it expected to run for?
January to December 2014.

Who is funding the study?
This research is being supported by the SRH Foundation, Heidelberg, Germany.

Who is the main contact?
Dr Thomas Günther Lesser
thomas.lesser@wkg.srh.de

Contact information

Type(s)
Scientific

Contact name
Dr Thomas Lesser

Contact details
Strasse des Friedens 122
Gera
Germany
07548

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The effect on parathyroid function of bilateral truncal ligation of the inferior thyroid artery during bilateral subtotal thyroidectomy: a randomised clinical trial

Acronym
PTF-ITAL (ParaThyroid Function Inferior Thyroid Artery Ligation)

Study objectives
Bilateral truncal ligation of thyroid arteries during subtotal thyroidectomies has no effect on parathyroid function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Association of Thuringia, 04/07/2012, ref: 35482/2012/77

Study design

Prospective randomized interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postoperative hypoparathyroidism (disorder of parathyroid function) following thyroidectomy

Interventions
Participants are randomized to one of the following two groups:
1. Non-bilateral truncal ligation of the inferior thyroid artery during subtotal thyroidectomy (control group)
2. Bilateral truncal ligation of the inferior thyroid artery during subtotal thyroidectomy (experimental group)

Intervention Type
Procedure/Surgery

Primary outcome(s)
Rate of clinically manifest hypoparathyroidism. Patients are asked about symptoms daily, in the morning and afternoon (i.e., paraesthesia in the face or hands, tingling periorally or in the fingers), and patients are clinically tested for Chvostek's and Trousseau's signs.

Key secondary outcome(s))
Incidence of postoperative asymptomatic hypocalcaemia and hypoparathyroidism, measured one day before the operation, intraoperatively at skin closure, and on postoperative days 2 and 5 during hospital stay.

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Adult patients (1880 years) with a multinodular non-toxic goitre
2. Normal serum albumin, total calcium and serum parathormone (PTH)
3. Normal vocal cord mobility

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
83

Key exclusion criteria
1. Thyroid volume >150 ml
2. Toxic goitre (including Grave's disease)
3. Patients admitted for either unilateral resection or resection of recurrent goitre
4. Parathyroid dysfunction
5. Renal insufficiency
6. Haematopoietic disorders
7. Abnormal calcium metabolism
8. Prior radioiodine therapy

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Strasse des Friedens 122
Gera
Germany
07548

Sponsor information

Organisation
SRH Wald-Klinikum Gera (Germany)

ROR
https://ror.org/00q236z92

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
SRH Foundation (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015	24/07/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes