

Total parathyroidectomy without autotransplantation and without thymectomy compared to total parathyroidectomy with autotransplantation and with thymectomy for secondary hyperparathyroidism (sHPT): a randomised controlled multicentred pilot study

Submission date 20/07/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 22/08/2006	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 06/01/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Total parathyroidectomy without autotransplantation and without thymectomy compared to total parathyroidectomy with autotransplantation and with thymectomy for secondary hyperparathyroidism (sHPT): a randomised controlled multicentred pilot study

Acronym

TOPAR

Study objectives

To compare different outcomes between total parathyroidectomy without autotransplantation and without thymectomy (TPTX) and total parathyroidectomy with autotransplantation and with thymectomy (TPTX+AT) over a three year follow up period.

On 14/08/2013 Austria was removed from the countries of recruitment, the anticipated end date was changed from 01/05/2011 to 30/11/2013, and the sponsor was changed.

The previous sponsor for this trial (up to 14/08/2013) was:

Study Centre of the German Surgical Society (SDGC) (Germany)
Im Neuenheimer Feld 110
Heidelberg
69120
Germany

The current sponsor can be found in the sponsor section below.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee (Kommission für Ethik in der Ärztlichen Forschung des Klinikums der Philipps-Universität Marburg) on the 21st August 2006 (ref: 113/06).

Primary study design

Interventional

Study design

Multicentre, randomised, controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Secondary hyperparathyroidism

Interventions

Group one: total parathyroidectomy without thymectomy and without autotransplantation (TPTX)

Group two: total parathyroidectomy with thymectomy and with autotransplantation (TPTX+AT)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Frequency of recurrent sHPT

Key secondary outcome(s)

1. Intraoperative:

1.1. Duration of surgical procedure

1.2. Expertise of responsible surgeon (estimated number of parathyroidectomies performed)

1.3. Complications and findings (number of parathyroid glands found, recurrent laryngeal nerve injury)

2. Post-operative until discharge:

2.1. Frequency of persistent hyperparathyroidism

2.2. Morbidity (e.g. bleeding, recurrent laryngeal nerve palsy)

2.3. Length of hospital stay

3. Discharge until 36 months follow up:

3.1. Frequency of recurrent sHPT

3.2. Frequency of autotransplantation due to refractory hypoparathyroidism

3.3. Frequency of reexploration of the neck or of the parathyroid autograft

3.4. Frequency of irreversible recurrent laryngeal nerve palsy

3.5. Follow up of clinical symptoms related to sHPT (change over time)

3.6. Change in quality of life

3.7. Death

Completion date

30/11/2013

Eligibility

Key inclusion criteria

1. Intact Parathyroid Hormone (PTH) more than or equal to a tenfold value above normal value

2. Age equal to or greater than 18 years

3. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Primary or tertiary hyperparathyroidism (hyperparathyroidism after kidney transplantation)
2. Familial hyperparathyroidism (MEN I, MEN II, hereditary hyperparathyroidism)
3. History of neck explorations for thyroid/parathyroid disease
4. Malignant disease of the thyroid glands
5. Bleeding disorder/coagulopathy
6. Severe psychiatric or neurologic diseases
7. Drug- and/or alcohol-abuse
8. Participation in another interventional-trial with interference of intervention and outcome
9. Inability to follow the instructions given by the investigator (e.g. insufficient command of language)

Date of first enrolment

01/11/2006

Date of final enrolment

30/11/2013

Locations

Countries of recruitment

Germany

Study participating centre

Dept. for Visceral, Thoracic and Vascular Surgery

Marburg

Germany

35033

Sponsor information

Organisation

Medical Faculty Philipps-University (Germany)

ROR

<https://ror.org/01rdrb571>

Funder(s)

Funder type

Government

Funder Name

German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (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?
Protocol article	protocol	18/09/2007	06/01/2021	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes