

# 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

<b>Submission date</b> 20/07/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/08/2006	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 06/01/2021	<b>Condition category</b> 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).

## **Study design**

Multicentre, randomised, controlled trial

## **Primary study design**

Interventional

## **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?
<a href="#">Protocol article</a>	protocol	18/09/2007	06/01/2021	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes