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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/08/2006	**Overall study status** Completed	
Last Edited 06/01/2021	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.sdgc.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Frequency of recurrent sHPT

Secondary outcome measures
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

Overall study start date
01/11/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Primary or tertiary hyperparathyroidism (hyperparathyroidism after kidney transplantation)
2. Familiary 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/coagolupathy
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, Thoraxic and Vascular Surgery
Marburg
Germany
35033

Sponsor information

Organisation
Medical Faculty Philipps-University (Germany)

Sponsor details
Baldinger Str.
Marburg
Germany
35033

Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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