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# Clips versus Ligatures in Thyroid Surgery

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| **Submission date**<br>16/12/2003 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>22/12/2003 | **Overall study status**<br>Completed | |
| **Last Edited**<br>02/10/2017 | **Condition category**<br>Surgery | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
KSC 02/2003

## Study information

**Scientific Title**

Clips versus Ligatures in Thyroid Surgery: a randomised controlled trial

## Acronym
CLIVIT-Trial

## Study objectives
To date, no clear scientific recommendation exists in regard to the available blood vessel ligation techniques in thyroid surgery. A systematic review comparing different blood vessel ligation techniques has not yet been performed. The literature on this topic shows several deficits thus reducing its internal and external validity. Main problems are underpowered sample sizes, missing data in regard to the surgical technique, lack of standardization of the various surgical techniques and of homogeneity of the used study designs.

Therefore a randomized controlled multicenter, patient-blinded, two-group parallel relevance study under standardized conditions is required in order to achieve high internal as well as external validity. This would allow the results to be generalized for thyroid surgery and also may have implications for other surgical settings. This study is one of the first studies designed and organized by the Study Center of the German Surgical Society (SDGC). Besides investigating the primary hypothesis, this study was also started with the aim of developing a nationwide structure for randomized trials using a common and surgical relevant procedure.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
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
Thyroid surgery

## Interventions
The standard surgical approach in both treatment groups will be the Dunhill-Procedure which consists of a hemithyroidectomy and a subtotal thyroidectomy (at least 2/3 of the gland). The randomisation will proceed when the thyroid gland has been exposed and the decision in favour

of a Dunhill procedure is made. Initially the vessels of the upper pole of the thyroid (hemithyroidectomy side) are localised and dissected from medial. Afterwards they are ligated with the conventional clamp-tie technique (Novafil 3-0 or equivalent monofilament suture type). Time is measured from ligating the vessels of the upper pole to the removal of the complete specimen. All vessels except the upper pole vessels of both sides are ligated according to the randomised technique: either using the clip vessel ligation technique or occluding manually by single ligatures (Vicryl 3-0).

### Intervention Type
Procedure/Surgery

### Phase
Not Specified

### Primary outcome measure
The primary objective of this study is to test whether there is a relevant reduction in operating time (>15 min), using the clip vessel occluding technique versus the conventional clamp-tie.

### Secondary outcome measures
Secondary objectives are divided into surgical and non-surgical categories. In the surgical category there are the following points: total duration of operation (skin incision until suture), weight of specimen, amount of postoperative bleeding, frequency of reoperation due to bleeding, recurrent laryngeal nerve paralysis (temporary or irreversible  pre- and postoperative assessment of vocal cord function by ENT-specialist), wound infection rate and rate of impaired parathyroid gland function. The non-surgical category consists of duration of postoperative hospital stay.

To assess the relevance of the chosen endpoints, the following ten aspects have to be ranked from "most important" to "least important" by patients and surgeons (only once): Intraoperative complications, postoperative complications, length of hospital stay, voice function, dysphagia, death, postoperative pain, postoperative fatigue, convalescence of complete physical maximum resilience and cosmetic result.

### Overall study start date
05/03/2004

### Completion date
31/12/2008

## Eligibility

### Key inclusion criteria
The trial population consists of hospitalised patients of the four participating Departments of Surgery, who are planned for an elective thyroid operation. These operations can be performed with either the clip vessel ligation technique or the conventional clamp-tie technique.

At study enrollment:
Age equal or greater than 18 years
Expected survival time more than 12 months
Patients with benign diseases of the thyroid gland scheduled for elective surgery
Euthyroid metabolism (normal level of TSH or T3/T4)

Normal function of the vocal cords
Informed consent

At the end of surgical exploration:
Suitable for at least 2/3 resection of the thyroid

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
420

### Key exclusion criteria
Malignant disease or high suspicion for malignancy (clinical and imaging evidence)
Nerve palsy
Graves' Disease
Coagulopathy
Current immunosuppressive therapy
Chemotherapy within 2 weeks before operation
Radiotherapy completed no longer than 8 weeks before operation
Severe psychiatric or neurologic disease
Drug- and/or alcohol-abuse
Participation in another intervention-trial with interference of intervention and outcome
Inability to follow the instructions given by the investigator or the telephone interviewer
Lack of compliance

### Date of first enrolment
05/03/2004

### Date of final enrolment
31/12/2008

## Locations

### Countries of recruitment
Germany

### Study participating centre
**University of Heidelberg Medical School**
Heidelberg

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# Sponsor information

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University of Heidelberg Medical School (Germany)

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### Sponsor type
University/education

### ROR
https://ror.org/038t36y30

# Funder(s)

### Funder type
Other

### Funder Name
Grant from the German Ministry of Research and Education and supported by the BBD-Aesculap© Company, Tuttlingen, 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 | 01/09/2006 | | Yes | No |
| Results article | results | 01/10/2012 | | Yes | No |