

# Clips versus Ligatures in Thyroid Surgery

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>16/12/2003   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>22/12/2003 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>02/10/2017       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data                                                         |

**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  
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## Sponsor information

### Organisation

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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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 01/09/2006   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/10/2012   |            | Yes            | No              |