

Clips versus Ligatures in Thyroid Surgery

Submission date 16/12/2003	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 22/12/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/10/2017	Condition category Surgery	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

Germany

69120

Sponsor information

Organisation

University of Heidelberg Medical School (Germany)

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

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?
Results article	results	01/10/2012		Yes	No
Protocol article	protocol	01/09/2006		Yes	No