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Incision in local anesthesia or operative removal of the tonsil to drain a collection of pus beside the tonsil (peritonsillar abscess)

Submission date
18/04/2016

Recruitment status
No longer recruiting

Registration date
07/06/2016

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A peritonsillar abscess, also known as quinsy, is a rare and potentially life-threatening complication of tonsillitis. It happens when an abscess (collection of pus) forms between one of the tonsils and the wall of the throat, causing pain, swelling and difficulty swallowing. For many patients, surgical treatment may be necessary in order to prevent further serious complications, such as blocked airways, lung infections or rupture (bursting) of the abscess. Most often, a small cut (incision) is made over the infected area so that the pus can be drained (incision and drainage procedure), although in some cases, the tonsils themselves are removed (tonsillectomy). Of these two procedures, it is unclear as to which is the most effective, in terms of pain relief, improvement on quality of life, time until recovery and recurrence (return) of the infection. The aim of this study is to compare these factors in patients receiving the incision and drainage, and tonsillectomy procedures.

Who can participate?
Adults with a peritonsillar abscess.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo the incision and drainage procedure under local anaesthetic (numbing injection). Those in the second group undergo a tonsillectomy while they are under a general anaesthetic (unconscious). After undergoing the procedures, participants in both groups remain in hospital for 5 days for observation. Before the procedure, participants are asked to score their level of pain, at rest and when swallowing, and then immediately after the procedure to judge their level of pain relief. Participants are asked about their pain levels every two hours the day after the procedure, and every three hours for the rest of their hospital stay. These questions are then repeated after one and six months.

What are the possible benefits and risks of participating?
There is no direct benefit from taking part in the study because all medical care provided is standard at the hospital. There are no notable risks other than the general risks involved with undergoing the procedures involved in the study, such as bleeding, pain, or allergy to antibiotics.

Where is the study run from?
University Medical Center Göttingen (Germany)

When is the study starting and how long is it expected to run for?
May 2015 to June 2024

Who is funding the study?
University Medical Center Göttingen (Germany)

Who is the main contact?
Dr Bernhard Weiss

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15/9/15

Study information

Scientific Title

Incision and Drainage or tonsillectomy for Treatment of PeriTonsillar Abscess: A prospective randomized clinical trial

Acronym
IDTPTA

Study objectives
Peritonsillar abscess treated by tonsillectomy is superior to incision and drainage in local anesthesia in subjective experience of peri- and postinterventional pain and is followed by increased patient satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-Kommission der Universitätsmedizin Göttingen, 04/01/2016, ref: 15/9/15

Study design
Prospective randomized controlled single-centre interventional clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Peritonsillar abscess

Interventions
Participants are randomly allocated to one of two groups using consecutively numbered envelopes including the decision for the treatment strategy.

Group 1: Participants receive the incision and drainage procedure which is performed under local anesthesia following an IV application of 1 g paracetamol. The patient lies in a 45° erected upper body. The mucosa will be anaesthetized superficially by lidocaine spray. After 3-5 minutes lidocaine will be injected at the maximum of mucosa protrusion for further local anesthesia. Following this, the abscess will be identified by punction with a 20 G needle. In case of pus aspiration an incision will be performed by scalpel, subsequently enlarged and opened using Hartmann’s forceps and the cavity completely emptied with the Eicken’s aspirator. The duration for this intervention is approximately 20 minutes.

Group 2: Participants receive a tonsillectomy, which is performed in an extracapsular approach in balanced total anesthesia. The patient lies in supine position with the neck extended dorsaly. After applying McIvar's mouth gag the tonsil will be luxated and the tonsil capsule identified with surgical scissors cutting the mucosa and spreading the tissue gently. Thoroughly following the capsule the tonsil is dissected out of its bed to thereby open up the abscess cavity. Anesthesia ends with applying 100 mg diclofenac suppository. The duration for this intervention is approximately 20 minutes.

After intervention, patients stay in hospital for five days for observation and i.v. application of antibiotics. After discharge from the hospital follow-up visits will be 1 and 6 month after intervention.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain is measured using the numeric rating scale (pain in rest, pain during swallowing) and the visual analogue scale (pain relief by intervention) at baseline before intervention (pain in rest, pain during swallowing) and directly after intervention (pain in rest, pain during swallowing and pain relief by intervention). Afterwards at the day of intervention the two questions to measure pain (pain in rest, pain during swallowing) are asked every 2 hours as well as 30 minutes before and 60 minutes after taking pain medication. From the first day after intervention on, the two questions are asked every 3 hours as well as before and after taking pain medication, and at 1 and 6 months.

Secondary outcome measures
1. Patient satisfaction is measured using the visual analogue scale (VAS) directly after intervention, at first day after intervention and before discharge
2. Required pain medication is measured by reviewing the records of the nursing team that regularly documents analgetics given to the patients
3. Trismus is measured using a metric tape measure at baseline before intervention and every day after during the hospital stay
4. Temperature is measured using a medical thermometer at baseline before intervention and every day after during the hospital stay
5. Inflammation is measured by white blood cells (WBC) and C-reactive protein (CRP) laboratory tests at baseline before intervention, at the second day after intervention and before discharge
6. Rate on pus drainage, required number of punctures and incisions, residual abscesses is measured during intervention and during follow up at hospital stay if re-interventions would be necessary
7. Complication rate is measured by documentation of all specific incidents occurring during hospital stay. When patients are seen for follow up at 1 and 6 month they are asked for the occurrence of special incidents
8. Specific (TOI-14) and general (15D) health related quality of life are measured using the Tonsillectomy Outcome Inventory 14 and the 15D-questionaire. The TOI-14 questionnaire is given to the patient at baseline and at 6 month follow up visit. The 15D questionnaire is given to the patient at baseline, the day after intervention, before discharge and at 1 and 6 month follow up visit.
9. Patient's benefit from otorhinolaryngological surgery and therapy is measured using the Glasgow Benefit Inventory at the 1 month follow up visit
10. Length of hospital stay is measured by prospective documentation

11. Time to full recovery and to resume work is measured using a response letter that is handed to the patient at discharge from hospital
12. Rate of recurrent tonsillitis, peritonsillar abscesses or two-stage tonsillectomy is measured by asking for this incidents at follow up visits 1 and 6 month after intervention
13. Microbial spectrum is measured using microbial swab sampling of the pus during drainage of the abscess

Overall study start date
25/05/2015

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Peritonsillar abscess
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
30 patients

Key exclusion criteria
1. Absence of informed consent
2. Secondary diagnosis that require regular analgetic medication
3. Psychiatric disorders (e.g. somatization disorder and affective disorders)
4. Pregnancy and breastfeeding
5. Chronic renal and liver disease
6. Gastric ulcer
7. Bone marrow diseases and diseases of the haematopoetic system
8. Medication of acetylsalicylic acid, coumarin derivatives or other anticoagulant medication in the last 10 days

9. Severe secondary diagnosis that go along with increased risk for general anesthesia
10. Limited cooperation or trismus severity that make Incision and drainage in local anesthesia impossible

Date of first enrolment
08/06/2016

Date of final enrolment
13/11/2022

Locations

Countries of recruitment
Germany

Study participating centre
Ludwig-Maximilians-University Hospital
Department of Otorhinolaryngology
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Sponsor information

Organisation
University Medical Center Göttingen

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/021ft0n22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
University Medical Center Göttingen

Results and Publications

Publication and dissemination plan
1. Planned publication of data after recruitment, analysis and paper work in peer reviewed journals
2. Planned presentation of data at scientific conferences

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			14/07/2025	No	No
Protocol file	version 1.2	01/09/2017	14/07/2025	No	No
Statistical Analysis Plan			14/07/2025	No	No