Rings, weddingbands and perioperative swelling of fingers

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24104

Source
NTR

Brief title
Rings&Fingers&Surgery

Health condition

Information about diseases is described in the section 'inclusion criteria'.

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Changes in circumference of digits 3 and 4 of both hands.

Secondary outcome

None

Study description

Background summary

In most hospitals, patients are not allowed to wear rings and wedding bands when they arrive at the operating theatre. They should be removed before entering the operating theatre. When sliding of the ring proves to be impossible, the ring must be cut by a ring-cutter.
The most important reasonings for this seems to be that perioperative swelling of the fingers might result in vascular obstruction with possible damage to the finger as a result.
Most doctors will agree that perioperative swelling does occur. However, the risk of swelling seems highly related to the type of the surgical procedure. Major surgery seems to have a much higher chance of swelling than minor procedure in day surgery. Unnecessary removal in the latter situation will result in cost and emotional damage to the patient.
Unfortunately, there are no data on perioperative swelling of fingers in elective surgical patients. The purpose of this study is to get more insight into the frequency and amount of perioperative swelling of fingers.

Study objective

Primary hypothesis/research question: Do fingers swell perioperatively in elective surgical patients?
Secondary hypothesis/research questions: Is the amount of swelling related to type of surgery, duration of surgery, the presence of an intravenous catheter in the ipsilateral hand, the application of positive pressure ventilation or prone position during surgery.

Study design

Patients are open for inclusion from September 23th 2019. Completion of the study is expected before January 2020.

Intervention

Measurement of the circumference of digits 3 and 4 of both hands in patients undergoing elective surgery. The circumferences are measured 1 hour preoperatively and subsequently 3, 24 and 48 hours postoperatively. Measurements are made by applying a short measurement tape around each proximal phalanx. To have a reproducible measurement, weights of 15 gram are connected to each end of the tape and the hand of the patients is positioned on a special frame. Then the hand and fingers of each hand are photographed, and each photograph is given a randomized number. Lateron, the circumferences of the fingers are determined by to separate individuals, who are unaware of the results of each other.

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Eligibility criteria

Inclusion criteria

1. Adult patients (19 years and older) planned for elective surgery which is not expected to influence the circumference of these fingers directly. E.g. no surgery of the shoulder, axilla, arm, hand or fingers, and no surgery which can be expected to affect the lymph drainage or blood vessels of these areas.
2. Patients can be assigned to one of these groups:
a. Surgical procedures in the supine position
i. Major non-cardiac surgery, such as colectomy, liver surgery, abdominal aortic surgery, Wertheim, radical prostatectomy, oesophagus resection, large hip surgery, etc.
ii. Cardiac surgery in which a heart-lung-machine was used
iii. Non-major surgery requiring at least a 24-hour postoperative stay in the hospital, e.g. jaw, plastic, ENT, gynaecological surgery.
iv. Non-major surgery in day care setting (patients do not stay a night in het hospital) (e.g. lumpectomy, cochlear implant)
v. Surgery below the umbilicus, performed under locoregional anaesthesia (no general anaesthesia/positive pressure ventilation).
b. Surgical procedures in the prone position

3. The patients should have no deformities, trauma or previous surgery which might prevent a reliable measurement of the fingers or the circumference of the fingers.
4. Patients should at least have one digit 3 or 4 on each hand.
5. Patients don’t suffer from infections, sepsis, kidney failure, they have no allergic reactions, are not pregnant, have no derangements of their cortisol metabolism.
6. Patients should not have an intravenous catheter for longer than one hour before the first preoperative measurement

Exclusion criteria

when no postoperative data on finger circumference can be obtained.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-09-2019
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-10-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8066
Other	METC Radboud University Medical Center : METC 2018-4799

Study results