

Rings, weddingbands and perioperative swelling of fingers

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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...

| | |
|-----------------------------|---|
| Ethische beoordeling | Positief advies |
| Status | Werving gestart |
| Type aandoening | - |
| Onderzoekstype | Observationeel onderzoek, zonder invasieve metingen |

Samenvatting

ID

NL-OMON24104

Bron

Nationaal Trial Register

Verkorte titel

Rings&Fingers&Surgery

Aandoening

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

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

when no postoperative data on finger circumference can be obtained.

Onderzoeksopzet

Opzet

| | |
|------------------|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | N.v.t. / één studie arm |
| Blinding: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

Deelname

| | |
|-------------------------|----------------------|
| Nederland | |
| Status: | Werving gestart |
| (Verwachte) startdatum: | 23-09-2019 |
| Aantal proefpersonen: | 150 |
| Type: | Verwachte startdatum |

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 03-10-2019 |
| Soort: | Eerste indiening |

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

| Register | ID |
|----------|----|
|----------|----|

| | |
|---------|--------|
| NTR-new | NL8066 |
|---------|--------|

Ander register METC Radboud University Medical Center : METC 2018-4799

Resultaten