Gownless Hand Surgery Trial

Published: 29-02-2024
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: To investigate whether the omission of surgical gowns during CTR and TVR surgeries affects postoperative wound infections

Ethical review	Not approved
Status	Will not start
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56666

Source
ToetsingOnline

Brief title
GHT

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
SSI, Surgical Site Infection

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Er is geen financiering aangevraagd voor het verrichten van dit onderzoek

Intervention

Keyword: Hand, Medical Waste, Surgical Attire, Surgical Wound Infection

Outcome measures

Primary outcome

Percentage of Surgical Site Infection withing 30 days after surgery

Secondary outcome

complications (wound healing, pain score (NRS))

environmental and economic impact of gown omission (CO2 reduction, savings in

euro*s).

Study description

Background summary

The question of whether surgical gowns truly impact infection rates in carpal tunnel release (CTR) or trigger finger release (TVR) surgeries remains largely unexplored, as existing stud-ies have failed to provide conclusive evidence. By conducting this randomized controlled trial, we aim to explore the impact of omitting surgical gowns during carpal tunnel release sur-gery and trigger finger release surgery on infection rates, as well as its potential positive ef-fects on the environment and hospital economics. Our hypothesis is that the findings demon-strate non-inferiority in postoperative infection rates, which would support the benefits of re-ducing gown usage, and lead to more sustainable and cost-effective surgical practices with-out compromising patient safety and care.

Study objective

: To investigate whether the omission of surgical gowns during CTR and TVR surgeries af-fects postoperative wound infections

Study design

Randomized Controlled Trial (RCT) single blinded

Intervention

Not wearing a surgical gown (as operating surgeon)

Study burden and risks

None

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients aged 18 and over
- Scheduled for carpal tunnel release surgery or trigger finger release
- Able to provide informed consent

Exclusion criteria

- Known immunosuppressive conditions or infections
- Previous history of hand surgery in the same hand
- Concomitant hand procedures?
- Corticosterid injection within 90 days before the operation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	220
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Not approved

Date:	29-02-2024
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL85925.099.24