Sterile versus Aseptic treatment in Dento-Alveolar Surgery*

Published: 14-09-2023
Last updated: 30-11-2024

The main objective is whether the standard use of non-sterile gloves and/or drapes can be a safe and a good alternative in dento-alveolar surgery. The second objective is to determine whether the use of non-sterile gloves or covering materials is...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON53179

Source
ToetsingOnline

Brief title
SADA

Condition

- Head and neck therapeutic procedures

Synonym
non-sterile gloves versus sterile gloves, post-operative infection

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: wetenschapsbijdrage Amphia Ziekenhuis

Intervention

Keyword: extractions, non-sterile surgical gloves, postoperative infection, wisdom tooth removal

Outcome measures

Primary outcome

Primary Objective:

Predictor: Use of sterile surgical gloves versus non-sterile gloves in

dentoalveolar procedures.

Outcome: Postoperative wound infection.

Objective: To exclude an increased risk (>=3%) of postoperative wound infection

after dentoalveolar surgery with non-sterile gloves compared to sterile gloves.

H0: There is an increased chance of >=3% of postoperative infection when using

non-sterile gloves compared to sterile gloves.

H1: There is a <3% increased chance of postoperative infection when using

non-sterile gloves compared to sterile gloves.

Secondary outcome

Secondary Objective(s):

Predictor: Use of sterile gloves versus non-sterile aseptic gloves in

dento-alveolar procedures.

Outcomes: Alveolitis, delayed wound healing, postoperative pain, after-effects.

Objective: To demonstrate or rule out a difference in postoperative

after-effects after dento-alveolar surgery with sterile materials versus

non-sterile gloves.

Predictor: Use of sterile gloves versus non-sterile clean gloves.

Outcomes: Torn or perforated gloves.

Objective: To demonstrate the safety of non-sterile operator and assistant

gloves

Study description

Background summary

The costs of health care have increased sharply in the past two decade, from 45 to 116 billion annually in the Netherlands. An uncontrollable rise in healthcare costs is a burden not only in a financial sense, but also in terms of sustainability, healthcare uses a lot of raw materials and produces an exceeding amount of residual waste. The 'Green Deal Sustainable Care' wants to focus on, among other things, reducing the use of raw materials and products, and where possible, and aims for a waste reduction of at least 25% in 2026 compared to 2018. However, the question is whether the necessary cost savings and waste reduction will be achieved. A critical survey of the usual procedures is therefore necessary.
Within dental practices, non-sterile procedures are mostly applied. Within OMF surgical care in a hospital setting however, standard procedure are sterile gloves and materials. The question is whether this contributes to safety of interventions in a treatment area (the mouth/pharynx) that is not sterile. Specifically, procedures in the field of dento-alveolar surgery (DA-Surgery) l. These are relatively low-complexity, high-volume procedures such as removal of teeth, root remains, wisdom teeth or inflammation. DA surgery in a hospital setting consists of around 400,000 procedures per year in the Netherlands. According to protocol, sterile gloves are used for all procedures within MKA surgery. These are relatively expensive and, because of the packaging per set, also produce a relatively large amount of residual waste that is difficult to separate. Nationally, this is estimated to be more than 700,000 pairs of gloves and 400,000 sterile drape sets on an annual basis. The use of non-sterile materials can not only result in a significant reduction in costs (5-7 times reduction), but in particular can contribute to the reduction of the amount of packaging material, raw materials, transport costs and residual waste

Study objective

The main objective is whether the standard use of non-sterile gloves and/or drapes can be a safe and a good alternative in dento-alveolar surgery. The second objective is to determine whether the use of non-sterile gloves or

covering materials is also a good alternative for the practitioner.

Study design

The study was designed as a pragmatic, monocenter, prospective, single blinded, randomized controlled study. The expected duration of the research is 2 years.

The patients are mainly referred by the dentist to the OMFS surgery.
the patient follows the regular protocol:
1. Intake and consultation for dento-alveolar surgery (removal of one or more teeth). During the consultation, the patient will be extensively informed about the indication for dento-alveolar surgery, technical aspects and possible after-effects/complications (standard procedure). In addition, the patient is informed about the possible participation in this study. Via the my Amphia app, the patient has already received information prior to this consultation about: the treatment, the practitioner, postoperative instructions and after-effects. In addition, information about the purpose of the study and access to the patient information folder of the study.
2. Depending on the patient's wishes and if the patient has already gone through the information folder at home, the consultation can be succeed by a treatment or this can result in an appointment for treatment.
3. If the patient chooses to participate in the study, randomization will take place to determine in which group (sterile versus aseptic) the patient will be placed. The patient is not informed in which group he/she has come (single-blind).
4. If indicated, the patient will receive a follow-up appointment for further treatment.
5. The patient is given an instruction folder, in which possible postoperative objections and possible complications are explained. This folder also clearly explains when the patient should contact us.
6. In case of complaints, the patient will contact the Amphia hospital and not the referrer (dentist or general practitioner). The post-operative complaints will be registered in Epic using the standard post-operative complaints module.
7. Postoperatively, the postoperative course will be followed by means of a digital questionnaire

Intervention

Sterile versus unsterile gloves/materials

Study burden and risks

The risk for the patients is very low, given the low expectation of difference in postoperative infection (based on theory and available literature). If there is a possible increased risk of postoperative infection, this can usually be

treated well and predictably with incision & drainage and/or antibiotics

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL
Scientific
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients who are eligible for dento-alveolar surgery (removal of one or more teeth) and can/want to undergo this treatment.
• Older or equal to 16 years
• ASA I, II or III
• Patient can understand and sign informed consent

Exclusion criteria

Exclusion Criteria
• Younger than 16 or not mentally competent/authorised.
• ASA IV or immunocompromised patients / using immunocompromising drugs.
• Indication for pre-/post-operative antibiotic use
• Postoperative antibiotic use for reasons other than postoperative infection.
• Patients who are unable to understand the explanations given, to read information leaflets and/or to report back any post-operative information

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2024
Enrollment:	2775
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	14-09-2023

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-06-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84284.100.23