Effect of post-operative chlorhexidine on complications and postoperative pain after surgical removal of lower impacted third molars: a randomized controlled trial

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Ethical review	Approved WMO
Status	Completed
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON54943

Source
ToetsingOnline

Brief title
Ritor study

Condition

- Head and neck therapeutic procedures

Synonym
alveolitis

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: stichting Wonderkaak van MKA chirurgen Zwolle en deel voor eigen kosten van de hoofdonderzoeker

Intervention

Keyword: chlorhexidine, third molar

Outcome measures

Primary outcome

Does rinsing with chlorhexidine after lower third molar removal effect the

postoperative complications?

Secondary outcome

• Does rinsing postoperative with chlorhexidine lower the postoperative pain

intensity, measured with the VAS scale, after surgical removal of impacted

lower third molars

• Does rinsing postoperative with chlorhexidine lower the need for analgesics

postoperative?

• Does rinsing postoperative with chlorhexidine reduces the number of

out-patient contacts?

• Does rinsing postoperative with chlorhexidine reduces / affect the number of

days of leave from work or study?

Study description

Background summary

One of the most common postoperative complications after the removal of a third molar is a condition known as dry socket. This term has been in use since 1896.

Since then several other terms have been used, including alveolar osteitis, postoperative alveolitis, alveolitis, sicca dolorosa and fibriniolytic alveolitis. Bim labelled the complication fibrinolytic alveolitis which is the most accurate of the terms, but also the least used. The condition has generally been characterised by delayed healing associated with degradadtion of clot, and is usually accompanied by persistent, radiating, pain postoperativively in and around the extraction site that is not easily relieved by analgesics6.

Because of the pain, swelling and trismus, patients also tend to have a greater need for painkillers. If it is possible to reduce the amount and severity of postoperative pain felt by patients the postoperative period would be more endurable, the quality of life will be less affected, and in addition to this it is possible that the amount of analgesics taken by patients after surgery could be lowered7. It can be a burden for both patients an surgeons and my result in a loss of productivity because at least 45% of patients require multiple visits to the surgeon.

Study objective

Many authors have advocated different methods of treating alveolar osteitis. One of these is the use of 0,12% chlorhexidine before and after the removal of the third molar. Despite many years of research, however, little progress has been made and so a study with large enough sample and standard outcome measures is warranted.

Goal of this study is assess the effect of postoperative use of chlorhexidine on postoperative complaints after surgical removal of a lower third molar.

Study design

Double blind, randomized controlled clinical trial

Intervention

Rising with chlorhexidine rinsing solution for one week three times a day

Study burden and risks

The risks of the use of chlorhexidine rinsing solution are very low. Patients can have a temporary disturbed taste and temporary discoloring of the teeth

Contacts

Public
Isala Klinieken

Kuyerhuislaan 3c
Zwolle 8024 PC
NL
Scientific
Isala Klinieken

Kuyerhuislaan 3c
Zwolle 8024 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients over 18 years of age referred for removal of a wisdom tooth in the mandible. Patient has ASA I.

Exclusion criteria

- Patient is younger than 18 years
- Patient has an ASA of II,III en IV
- Patient has only one maxillary third molar that needs to be extracted/removed
- Patient has an active pericoronitis
- Patient has trismus
- Patient has chronic pain

- Patient is pregnant
- Patient has a known allergy for ibuprofen of other NSAID*s
- Patient has a known allergy for articaine of epinefrine
- Patient has a known allergy for gentamicin
- Intra-operative compliations for example excesive bleeding

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-07-2021
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO Date:	30-03-2021
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	30-03-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27406
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71727.075.20
OMON	NL-OMON27406