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The effectiveness of clove oil as a topical anesthetic in reducing pain during needle insertion

Submission date
18/10/2023

Recruitment status
No longer recruiting

Registration date
18/10/2023

Overall study status
Completed

Last Edited
10/11/2023

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental procedures can be distressing for children, often attributed to the pain experienced during an inferior alveolar nerve block (IANB), a common local anesthesia technique. This study endeavors to address this issue by comparing the efficacy of two analgesic agents: clove oil and 20% benzocaine gel.

Clove oil, derived from the clove plant, has shown promise as a natural analgesic with potential benefits in dentistry. Benzocaine gel, a synthetic local anesthetic, is a conventional choice for pain management during IANB. However, the comparative effectiveness of these two agents in pediatric patients remains largely unexplored.

Who can participate?
Children aged 7-11 years requiring non-urgent dental treatment under IANB.

What does the study involve?
Children were divided into two groups, with an equal number of kids in each group. This study was "double-blind," meaning that both the doctors and the statistician didn't know which group each child belonged to.

In the first group (called the control group), a 20% benzocaine gel was used, while the second group received clove oil. Before applying these substances, the area where the injection would happen was dried. Then, 0.3 mL of each pain-relief product was applied using a cotton roll, and it stayed there for 3 minutes.

A pediatric dentist administered the inferior alveolar nerve block (IANB), which was recorded on a mobile device (Mi 9, Xiaomi) to measure how much pain the participant was feeling by looking at the facial expressions.

What are the possible benefits and risks of participating?
Possible benefits are: Performing non-urgent dental treatment in the mandibular arch such as,

pulpotomy, serial extraction, and pulpectomy.
Possible risk is: IANB will be painful if the topical anesthetic is not effective.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2022 to October 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Mawia Karkoutly

ORCID ID
http://orcid.org/0000-0003-0227-1560

Contact details
Mazzeh Highway
Damascus
Syria
-
+963 992647528
mawia95.karkoutly@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Funder No. 501100020595

Study information

Scientific Title

The effectiveness of clove oil as a topical anesthetic for healthy children during inferior alveolar nerve block: a randomized controlled trial

Study objectives
The null hypothesis was that no statistically significant difference would be noted in efficacy of clove oil and benzocaine 20% gel in reducing pain from needle stick in children during the inferior alveolar nerve block.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/05/2022, Ethical and Scientific Committee of Damascus University (Damascus University, Mazzeh Highway, Damascus, -, Syria; +963 992647528; dean.dent@damascusuniversity.edu.sy), ref: N1770

Study design
Doubleblind randomized parallelgroup active-controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dental pain

Interventions
Children were randomly assigned into two groups in a ratio 1:1 using simple randomization method. The same number of children were randomly allocated to each intervention arm using randomization online software: https://www.randomizer.org. This was a double-blind trial where clinicians and statistician were blinded to which interventional arms children are assigned to.

20% benzocaine gel was applied for the first group (control group), and clove oil was applied for the second group. Mucosa drying was applied at the site of injection before application of the tested material, then 0,3 mL of each topical anesthetic was applied using a cotton roll for 3 minutes. IANB was performed by one pediatric dentist, and the child was videotaped using a mobile device (Mi 9, Xiaomi). The injection was made more posteriorly and slightly lower since the mandibular foramen is situated at a level lower in the pediatric patient. Therefore, the barrel of dental carpule syringe (Dental carpule syringe, Dental Laboratorio) was directed on the plane between the two primary molars on the opposite site of the arch, then a 27-gauge x 21 mm

needle (Disposable Dental Needle, Shanghai Dochem Industries Co., Ltd.) was inserted, and 1.8 mL of 2% lidocaine with epinephrine 1:80,000 (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam) was injected.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
20% benzocaine gel, clove oil, 2% lidocaine with epinephrine 1:80,000

Primary outcome measure
1. The sound, eyes, and motor (SEM) scale was used to measure pain objectively during injection, and it evaluated by a blinded outcome assessor using the recorded video.
2. The Wong–Baker Faces Pain Rating Scale (WBFPS) was used to subjectively assess pain since children were asked to select the face that represented their pain level immediately after the IANB administration.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
09/03/2022

Completion date
20/10/2022

Eligibility

Key inclusion criteria
1. Healthy children.
2. Children aged 7-11 years.
3. Children with no previous dental experience.
4. Children requiring non-urgent dental treatment under IANB.

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit

11 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Children are allergic to any anesthetic agent used in this study.
2. Children with fascial space infections and/or dental abscesses.
3. Special health care needs children.
4. Children have odontophobia.

Date of first enrolment
20/06/2022

Date of final enrolment
20/10/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh Highway
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
Mazzeh Highway
Damascus
Syria
-
+963 992647528
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://www.damascusuniversity.edu.sy

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Mawiamaherkarkoutly@hotmail.com

IPD sharing plan summary
Available on request