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Evaluation of non-instrumentation endodontic treatment in necrotic primary molars using a modified mixture of three antibiotics with simvastatin

Submission date
07/08/2021

Recruitment status
No longer recruiting

Registration date
13/09/2021

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate the success rate of non-instrumentation endodontic treatment using a modified antibiotic paste of cefexime, ciprofloxacin and metronidazole with simvastatin (an anti-inflammatory, bone regeneration drug) on necrotic (dead) primary molars compared to traditional pulpectomy (complete removal of the pulp of the teeth).

Who can participate?
Children aged 4-8 years old with necrotic primary second lower molars

What does the study involve?
Participants will be randomly divided into two groups to be treated with antibiotics in non-instrumentation endodontic treatment or conventional root canal treatment. All the teeth will be evaluated after 1, 3, 6, and 12 months clinically and 3, 6, and 12 months radiologically (x-ray).

What are the possible benefits and risks of participating?
Because of the complexity of the root canal system in primary molars, long or multiple visits are needed to complete pulpectomy treatment, especially with non-cooperative children. Non-instrumentation endodontic treatment seems to be a good alternative choice to traditional pulpectomy as it's an easier and less time-consuming treatment.

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

When is the study starting and how long is it expected to run for?
March 2018 to January 2021

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2851

Study information

Scientific Title
Clinical and radiological evaluation of modified triple antibiotic paste and simvastatin in non-instrumentation endodontic treatment of necrotic mandibular primary molars: a randomised controlled clinical trial

Acronym
3Mixtatin in NIET

Study objectives

This study is designed to assess the hypothesis that non-instrumentation endodontic treatment with 3mixtatn can be a good alternative treatment to traditional pulpectomy of necrotic primary molars.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2018, Damascus University, Faculty of Dentistry (University of Damascus Dental School, Damascus, Syria; +96390404840; Osama.aljabban@gmail.com), ref: none provided

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Patient information sheet in Arabic: https://drive.google.com/file/d/1FiNwH5tskC1Ycgvjg468fXKny86a3gl2/view?usp=sharing

Health condition(s) or problem(s) studied
Necrotic primary molars

Interventions
Forty-two necrotic mandibular primary second molars from healthy children aged 4-8 years will be randomly divided into two groups using http://www.randomization.com:
Group A: teeth will be treated with 3mixtatin in non-instrumentation endodontic treatment
Group B: teeth will be treated with conventional root canal treatment

After local anesthesia using mepivicaine hydrochloride 3%, each tooth will be isolated using the rubber dam. The carious lesions will be removed and the access cavity will be prepared with a bur in a high-speed handpiece. In group A the canal orifices will be enlarged with a round bur (1 mm diameter and 2 mm depth). The pulp chamber and the canal orifices will be irrigated with 17% EDTA to remove the smear layer and the dentin permeability increased with chemical solutions and then with physiological serum, followed by irrigation with 10 ml 5.25% sodium hypochlorite to remove the necrotic tissues, then irrigated with physiological serum and finally with chlorhexidine gluconate 0.2%.

This irrigation protocol will be administered in both two groups.

3Mixtatin preparation:
The three commercially available antibiotics metronidazole, cefixime and ciprofloxacin will be mixed in a ratio of 1:1:1 with 2 mg of simvastatin after removing the coating materials and pulverized by porcelain mortars and pestles. The 3Mixtatin will be mixed with propylene glycol to obtain a creamy mix and placed over the canal orifices and the pulpal floor. The tooth will be sealed with a glass ionomer cement and then restored with a stainless steel crown.

In group B conventional root canal treatment will be done using k-files and h-files and using the previously mentioned irrigation protocol in group A.

The root canals will be dried with paper points and obturate with zinc oxide eugenol paste using a Lentulo spiral in a low-speed handpiece. The tooth will be sealed with a glass ionomer cement and then restored with a stainless steel crown.
All procedures will be administered by a pediatric dentist.
All the teeth will be evaluated after 1, 3, 6, and 12 months clinically and 3, 6, and 12 months radiologically.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical success criteria measured by two external examiners at baseline (T0) directly after the treatment, 1 month (T1), 3months (T2), 6 months (T3), and 12 months (T4):
1. Absence of fistula detected visually
2. Absence of painful symptoms measured using The Universal Pain Assessment Tool (UPAT)
3. Absence of pathological tooth mobility assessed by applying alternate pressure on the outer and inner aspects of the crown of the tooth using two hand instruments. The results were recorded using a mobility index.
4. Intact gingival contour detected by palpation

Radiographic success criteria measured at baseline (T0), 3 months (T1), 6 months (T2), and 12 months after treatment (T3):
1. Resolution of furication lesion radiolucency analysed on the follow-up radiographs using (Imagej)(fiji) 2019 software
2. Absence of pathological bone resorption assessed by detecting any new radiolucency on radiographs
3. Absence of pathological root resorption analysed on the follow-up radiographs using (Imagej) (fiji) 2019 software

Secondary outcome measures
The duration of treatment in each group, recorded directly after the treatment

Overall study start date
05/03/2018

Completion date
15/01/2021

Eligibility

Key inclusion criteria

1. Child aged 4-8 years old with no systemic diseases
2. Necrotic primary second lower molars with signs or symptoms of loss of vitality: buccal swelling or sinus, pathological mobility, bifurcation or periapical radiolucency, pathological root resorption

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
44

Total final enrolment
44

Key exclusion criteria
1. Non-restorable teeth
2. Excessive root resorption involving more than half of the root
3. Perforation of the pulpal floor
4. Facial cellulitis cases
5. Noncooperative patient
6. Patient with history of allergy to one of the used drugs
7. Patient with systemic disease

Date of first enrolment
05/09/2018

Date of final enrolment
18/05/2020

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dentistry

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Sponsor information

Organisation
Damascus University

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University/education

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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. The study protocol and statistical analysis plan aren't available yet.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2024	04/10/2024	Yes	No