Informed Consent

Official Title:

Clinical and Microbiological Evaluation of the Chemo-mechanical Caries Removal Agent (BRIX3000®) in Primary Molars: A Randomized Controlled Clinical Trials.

NCT number:

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Date of the document:

20/09/2019

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Title of Research:

Clinical and Microbiological Evaluation of the Chemo-mechanical Caries Removal Agent (BRIX-3000) in Primary Molars: A Randomized Controlled Clinical Trial.

Part I – Research Participant Information Sheet:

A. Purpose of the Research:

To perform clinical and microbiological studies to confirm manufacturer's claims by comparing this novel chemo-mechanical agent (BRIX-3000) and the previously-available chemo-mechanical agent (Carie-Care™) to the conventional surgical method for caries removal in primary molars.

It may be recommended as a promising alternative treatment modality for children, who fear to visit clinics for getting dental treatments, if this material showed an increased efficacy, efficiency with decreased pain experienced during caries removal.

B. Detailed Description of the Research:

This study will be carried out at King Abdulaziz Dental University Hospital (KAUDH)

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and Microbiology Research Laboratory at Faculty of Pharmacy in King Abdulaziz University, Jeddah, Saudi Arabia. The study sample will be consisted of 60 children aged 4-9 years without sex predilection, who will attend as outpatients to the Department of Pediatric Dentistry at KADUH during the period from July 2019 to July 2020. The included teeth (n=120) will be assigned randomly into one of the following groups according to the decay removal technique that will be utilized using two-arm parallel groups with split-mouth design:

The control group: (n=60) primary molars will be subjected to removal of caries using a conventional drilling method using carbide dental burs.

The experimental group (BRIX-3000): (n=30) primary molars will be subjected to removal of caries using a chemo-mechanical agent (Brix-3000)

The experimental group (Carie-Care™): (n=30) primary molars will be subjected to removal of caries using a chemo-mechanical agent (Carie-Care™). The study design is experimental, randomized controlled clinical trial with two-arm parallel groups and split-mouth design following the "Consolidated Standards of Reporting Trials (CONSORT,2010)" statement.

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C. Potential Risks and Discomforts:

Temporary post-operative pain.

Temporary numbness of lip and cheeks due to local anesthesia.

D. Potential Benefits:

Elimination of the infection and pain associated with dental caries with better oral health related quality of life.

E. Cost/s To participate in the research you will bear no additional costs or extra loss.

F. Compensation / Treatment:

In the event of injury resulting from participation in this research study, Researcher will make a treatment to you, its facilities and professional attention. Financial compensation from KAUFD is not available.

G. Voluntary Participation:

Participation in this study is voluntary. You will suffer no penalty nor loss of any benefits to which you are otherwise entitled should you decide not to participate. Withdrawal from this research study will not affect your ability to receive alternative methods of Dental care available at KAUFD.

Significant new findings developed during the course of the research study which might be reasonably expected to affect your willingness to continue to participate in the research study will be provided to you.

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H. Confidentiality:

Your identity and medical record, as a participant in this research study, will remain confidential with respect to any publications that may result from this study. Furthermore, your Dental/medical record may be reviewed by the Research Advisory Council or the agency sponsoring this research in accordance with applicable laws and regulations.

I. Contact Person(s):

DR. Manal Maashi

A signed copy of the consent form will be given to you.

PART II - Authorization for performance of certain procedures:

1. I/surrogate authorize Dr. Manal Maashi and his/her associates to administer the following drugs, use the following devices or perform the following procedures during my treatment (or the treatment of the person named above for whom I am responsible)

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached Research Participant Information sheet and that **Dr. Manal Maashi** has explained to me the nature of the procedures described in the Research Participant Information Sheet as well as any benefits ~~reasonably~~ to be expected, possible alternative methods of treatment, the attendant discomforts and risks reasonably to be expected and the possibility that complications from both known and unknown causes may arise as a result thereof. I was given ample opportunity to comprehensively inquire about this study and procedures and all my questions were answered to my satisfaction.

3. I understand that I am not entitled for reimbursement for expenses incurred as a result of my participation in this study

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4. I voluntarily accept the risks associated with the above-mentioned procedures with the knowledge and understanding that the extent to which they may be effective in my treatment (or the treatment of the patient named above, as the case may be) has not been established, that there may be side effects and complications from both known and unknown causes and that these procedures may not result in cure or improvement.

5. I understand that I am free to withdraw this consent and discontinue treatment with the above procedures at any time. The consequences and risks, if any, which might be involved in the event I later decide to discontinue such treatment, have been explained to me adequately. I understand that such withdrawal will not affect my ability to receive any dental/medical care made necessary by the performance of such studies or to which I might be otherwise entitled.

6. I confirm that I have read, or had read to me, the foregoing authorization and that all blanks or statements requiring completion were properly completed before I signed.

Patient Name:_____

File #: _____

Patient/Surrogate: _____
(If signed by Surrogate)

Relationship: _____

Signature Date

_____ _____

7. I confirm that I have accurately translated and/or read the information to the subject or his/her surrogate.

Name: Manal Suliman Maashi
Signature: _____

KAUFD ID #: 1700528
Date: 19/5/2019

8. I have fully explained to the above patient/ relative/ guardian the nature and purpose of the

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foregoing procedures, possible alternative methods of treatment which might be advantageous, the reasonable benefits to be expected, the attendant discomforts and risks involved, the possibility that complications may arise as a result thereof and the consequences and risks, if any, which might be involved in the event the patient/ relative/ guardian hereafter decides to discontinue such treatment.

It is my understanding that the above patient/ relative/ guardian understands the nature, purposes, benefits, and risks of participation in this research before signing ~~of~~ this informed consent. I have also offered to answer any questions the above patient/ relative/ guardian might have with respect to such procedures and have fully and completely answered all such questions.

(Signature of Principal Investigator/ Delegate):

Print Name: Dr. Heba Mohamed Elkhodary

Title: Associate Professor in Pediatric Dentistry

Date: 19/5/2019

Chairman of REC.KAUFD