Graftless Closed Sinus Tenting Using Dental Implants After Densah Burs Osteotomy Versus Conventional Osteotomy in Localized Sinus Pneumatization: a Randomized Clinical Trial

Thesis Protocol Submitted for Partial Fulfillment of the Requirements for Master's Degree In Oral & Maxillofacial Surgery Faculty of Oral & Dental Medicine - Cairo University

By

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Code: OMFS 3-3-5





Faculty of oral & dental medicine Cairo University Research Ethics Committee <u>Application Form</u> Human Subjects

Kindly fulfill the following:

Research title:

Graftless closed sinus tinting using dental implants after Densah bur osteotomy versus conventional osteotome in localized sinus pneumatization. A Randomized clinical Trial.

Master	[/]	PHD/D []	others []
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Full name of the researcher: Basma Mohammed Abdelfatah Mohammed Shaheen

Research Objective:

Compare the quantity of bone gained by using Densah bur (osseodensification) versus the osteotome in closed sinus lifting used as control group.

Number of visits & follow up period:

After one week and after 6 months

Direct benefit of the research to the human volunteer:

- Caregivers and children will be taught the correct way to brush teeth with the help of models and life manifestations.
- Preventive advice will be provided at the visit and information will be requested on dietary habits and oral hygiene and how to improve them in the future.
- Restoring missing teeth

The scientific interest and the desired public benefit of the research:

Determining the amount of bone gained in graftless closed sinus tinting using dental implants by Densah bur osteotomy versus conventional osteotome in localized sinus pneumatization

Providing the Egyptian society with data related to the oral health status of orphan patients and the impact of their diet on them





Side effects and the degree of risk and expected to occur and how to deal with the:

- Pain
- Oedema
- Sinus membrane injury

Patients will be prescribed:

- Augmentin 1gm every 12 hours for one week
- Brufen 600 mg every 8 hours
- Alphintern 2 tablets before food every 8 hours for 5 days.

Patient's full knowledge of the research steps: Reading [v] Oral explanation [v] Other []

1. I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.

2. The researcher has informed me of the possible therapeutic alternatives for this research.

3. The researcher has informed me of all the possible risks of this research and how to deal with it.

4. I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.

5. I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines, food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions. For my health

6. I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher physician if I enter any other research throughout the period of this research.

7. I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.

After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons.





The physician in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as replacing names with code numbers or hiding facial features when photographing (etc.).

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Signature:

د. محمد على ت 16/10/2021

Date:

هذا البحث تمت موافقة اللجنه عليه برقم