Title: A Clinical Trial of Locally Made Titanium Miniplate and Screw in Maxillofacial Fractures Management

NCT04279925

Ethical Clearance ID: 1085/UN2.F1/ETIK/PPM.0002/2019

Date of Document: 24/04/2022

CONSENT SHEET TO PROSPECTIVE SUBJECTS

I, **dr. Prasetyanugraheni Kreshanti, SpBP-RE (KKF)** / Research Team [**dr. Dwi Wicaksono, dr. Vika Tania, SpBP-RE (KKF)**] chaired by myself, **dr. Prasetyanugraheni Kreshanti, SpBP-RE (KKF)** from the Division of Reconstructive and Aesthetic Plastic Surgery FKUI-RSCM will conduct a research entitled **A Clinical Trial of Locally-Made Titanium Miniplate and Screw in Maxillofacial Fractures Management**.

I will provide information to you (Mr/Mrs) about this research and invite you (Mr/Mrs) to be a part of this research.

You can participate in this research by signing this form. If you agree to participate in this research, you can freely withdraw from this research at any time. You also have the right to receive the latest information from us regarding the treatment being tested, if any. If you refuse to participate or withdraw from this research, that decision will not affect your relationship with me and will not affect the services that apply at this hospital.

If you do not understand any statement in this form, feel free to inquire to me.

1. Research objectives

The purpose of this study was to examine the effectiveness of locally produced titanium facial implants in the management of facial fractures. Its effectiveness will be compared to imported implants which are very expensive. In addition, in the future, it is hoped that these locally made implants can be mass produced and used in all hospital institutions in Indonesia

2. Participation in research

Overall, this research will run for 3 months. If you decide to participate in this research, you will be asked to agree to follow our schedule and ensure that you can comply with the schedule. This research will be conducted if you are undergoing surgery to repair and restore the position of the shifted facial bones to a normal shape so that the function of vision and chewing (bite) returns to normal. One day after surgery and at the end of the third month, you will undergo a head CT scan to compare the bone density resulting from the implant installation process, both locally made implants and imported implants.

3. Why we chose you

You were chosen to undergo this study because there was a facial fracture in the middle of the face that occurred less than 2 weeks ago. If the fracture is not repaired, it will interfere with functions such as eyeball movement that is not free in all directions, double vision and an asymmetrical face shape.

4. Research procedure

4a. Intervention procedure

1. You will be instructed to bathe with 4% chlorhexidine soap, which is also performed on all patients undergoing surgery at RSCM

2. You will be asked to fast for 6 hours before surgery, which is also done on all patients undergoing surgery at RSCM

3. In the operating room when you are anesthetized you will receive an injection of antibiotics to prevent post-operative infection

4. Intraoperatively the surgeon will place screws on your upper and lower jaws and then maintain their position using wires to maintain your normal bite position

5. Then the surgeon will make an incision according to the location of your facial fracture, then look for the fracture line and free it from attachment to the surrounding soft tissue

6. The surgeon will repair and restore the position of the bone to its normal position

7. The surgeon will receive an envelope that has been randomized before. The envelope contains instructions for using implants, whether they are domestically produced implants or imported implants. For example, on your face there are 3 fracture lines, then you will be installed with 3 implants with a combination of installation: 3 domestically made implants/2 domestically made implants and 1 imported implant/1 domestically made implant and 2 imported/3 implants import. This is pre-determined through a tested random method. In other words, it is not the surgeon who determines the type of implant that will be placed on you

8. The implant is placed above the fracture line to ensure that the bone does not shift again

9. Post surgery your normal bite position (upper and lower jaw) will be maintained for 2 weeks so that it does not change so that you will be able to chew food properly as before surgery.

10. For 2 weeks you will consume liquid food from the mouth

11. 1 day postoperatively and at the end of the 3rd postoperative month you will undergo a CT scan of the head to compare bone density, see if there are loose screws on implants, either domestically produced or imported implants

12. Post-surgery while you are being treated you will receive injections of antibiotics and painkillers through an IV line

13. 2 days after surgery you can go home and undergo follow-up treatment at the RSCM plastic surgery outpatient clinic. Infusion drugs previously obtained will be replaced with drugs that can be taken orally

14. You will be asked to check once a week for 3 weeks to see if there are signs of inflammation or infection that occur

4b. **Available or current intervention procedure**

Currently, importyed implants are used to maintain the position of facial bones that were repaired during surgery.

5. Risks, side effects and management

1. Any foreign object that enters the human body will be at risk for infection. So far, titanium implants are commonly used for surgery in patients with facial fractures, with very rare side effects.
2.
3. However, if an infection occurs, you will be treated according to the applicable standard operation procedure, with the provision of antibiotics as initial treatment until the possibility of implants being removed (both locally produced implants and imported implants).

6. Benefits

The benefits that you can get by joining this research is by contributing in the development of domestic product development that have the opportunity to become products that will compete with imported products have existed.

7. Compensation

You will get a total transportation fee of [Rp 200,000] when you are done with all the research protocol, given 3 months after surgery.

8. Financing

This research received a grant from the Ministry of Research and Technology of the Republic of Indonesia. Prior to the study on humans, this implant has gone through various tests, both technical material testing at the Universitas Indonesia Faculty of Engineering, studies on animal at Bogor Agricultural Institute, all resulting in locally made implants in par with imported implants. This clinical trial in humans is the final stage before these locally made implants can be mass-produced and used in hospitals all around Indonesia.

9. Confidentiality

All data collected in this study will be kept confidential. Presentation of research results in scientific meetings/conferences and publications in scientific journals will not include your name. However, representatives from the Ministry of Research, Technology and Higher Education of the Republic of Indonesia, the ethics committee of the UI Faculty of Medicine, and the competent national authorities will have access to research data for verification.

10. Obligations of research subjects

As a participant in this research, you are obliged to follow the rules or research instructions as written above. If something is not clear, you can ask the research team further. During the study, you will be required to consume liquid diet for 2 weeks. Follow up visit to the outpatient clinic is necessary for 1 week, 2 weel, 3 week, 5 week, 8 week, and 9 week post surgery. You will need to undergo a head CT scan evaluation at 1 day and 3 months postoperatively.

11. The right to refuse and resign from research

You do not have to participate in this research if you do not wish to. You should understand that even if you agree to participate, you have the right to withdraw from this research. If you refuse to participate or withdraw from this research, that decision will not affect your relationship with me and will not affect the standard of care that applies at this hospital.

Additional information

You are given the opportunity to ask all things that are unclear regarding this research. If any side effects occur at any time or you require further explanation, you can contact **dr. Prasetyanugraheni Kreshanti, SpBP-RE (KKF) at +628158732424.**

INFORMED CONSENT AS RESEARCH SUBJECT

All these explanations have been conveyed to me and all my questions have been answered by the doctor. I understand that if I need an explanation, I can ask dr. Teuku Nanda Putra

Approval Certification (*Consent*)	
I have read all the descriptions about this research. I have been given the opportunity to ask and all my questions have been answered clearly. I am willing to participate in this research study voluntarily. _____ Name of the subject/guardian _____ Signature of the subject/guardian Date_____ day/month/year	I confirm that this participant has been given the opportunity to ask questions about this study, and all questions have been answered correctly. I confirm that consent has been given voluntarily. _____ Name of the researcher _____ Signature of the researcher Date _____ day/month/year

Researchers' Information:

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