ISRCTN11838566 https://doi.org/10.1186/ISRCTN11838566

A multicenter randomized clinical study of using a three-dimensional printed patient personalized titanium plate in jaw surgery

Submission date
21/05/2022

Recruitment status
No longer recruiting

Registration date
06/06/2022

Overall study status
Completed

Last Edited
26/06/2024

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Jaw surgeries commonly use a titanium alloy for bone fixation for many characteristics such as its light weight, high strength, corrosion resistance and good biocompatibility. The most commonly used plates for bone fixation are commercially available and are produced and casted according to the fixed shape of the mold, but the irregular shapes of jaw bone surfaces make these commercially available plates unable to completely fit to the contour of different bone surfaces and need bending to get an appropriate approximation between the bone parts. Plate bending wastes operation time, increases the operation risk and sheds off the protective surface of the titanium plate. Therefore, the construction of 3D-printed patient personalized titanium plates will overcome such problems in bone fixation. The aim of this study is to assess using a 3D-printed patient personalized titanium plate in jaw surgery.

Who can participate?
Patients aged 18-45 years with dentofacial (teeth/face) deformities requiring jaw surgery

What does the study involve?
The patients are randomly divided into the 3D printed personalized titanium plate group and the commercial titanium plate group. The follow-up for the treatment is 6 months after the jaw correction surgery and at the end of the sixth month the patients will be admitted for the removal of the titanium plates.

What are the possible benefits and risks of participating?
There is evidence that 3D-printed personalized titanium plates can improve the accuracy of jaw surgery, reduces the operation time and minimizes risks during the operation. The participants' condition may or may not improve moreover or there may be the following risks and discomfort. Although the titanium alloy material in this study has been tested in animals to ensure the safety of the product before its use in a clinical trial, uncertainty still exists regarding its clinical effects. Risks associated with the surgery include swelling, general rejection, local infection and inflammation, and wound dehiscence (separation of the edges of a surgical wound).

Where is the study run from?
West China Hospital of Stomatology, Sichuan University (China)

When is the study starting and how long is it expected to run for?
January 2020 to June 2024

Who is funding the study?
West China Hospital of Stomatology, Sichuan University (China)

Who is the main contact?
Dr Wael Telha
doctorzhu@scu.edu.cn

Contact information

Type(s)
Principal investigator

Contact name
Dr Wael Telha

Contact details
No. 14, Section 3
Ren Min Nan Road
Chengdu
China
610041
+86 (0)19182163717
doctorzhu@scu.edu.cn

Additional identifiers

Protocol serial number
LCYJ2020-YF-1, ChiCTR2200060289

Study information

Scientific Title
A prospective, multicenter, randomized, clinical controlled trial of using a three-dimensional printed patient personalized titanium plate in orthognathic surgery

Study objectives
This study is designed to compare the effect of using a 3D printed personalized titanium plate and commercially available titanium plates in orthognathic surgery on the operation time and the accuracy of post-operative bone positioning.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 24/06/2020, Medical Ethics Committee, West China Hospital of stomatology, Sichuan University (Hospital Management Office, West China Medical Center, Building 1, West China East Campus, no. 28 South Telecom Street, Wuhou District, Chengdu, China; +86 (0)28-85503401; yxglc@scu.edu.cn), ref: not provided

Primary study design
Interventional

Study design
Prospective randomized multi-center interventional clinical trial study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Management of dentofacial deformities through an orthognathic surgical intervention

Interventions
A prospective, randomized multi-center clinical trial study planned to compare the accuracy of bone positioning following orthognathic surgery between 3D printed personalized titanium plates patient group and traditionally available titanium plates. The patients are randomly divided into the 3D printed personalized titanium plate group and the commercial titanium plate group. This study could not be blinded to surgeons, but the participants and evaluators are blinded. The follow-up for the treatment is 6 months after the jaw correction surgery and at the end of the sixth month the patients will be admitted for the removal of the titanium plates.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
3D-printed personalized titanium plates

Primary outcome(s)
The accuracy of using 3D printed titanium plates through evaluation of the post-operative CT scan with the pre-operative 3D planning using a 3D Slicer software program

Key secondary outcome(s)
Current secondary outcome measures as of 05/06/2024:

Long-term stability of the 3d printed personalized plates used in orthognathic surgery Any abnormalities related to the use of 3D plating were assessed using a blood sample before and after the surgery

———

Previous secondary outcome measures:

Any abnormalities related to the use of 3D plating assessed using a blood sample before and after the surgery

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Patients with dentofacial malformations requiring orthognathic surgery
2. Aged 18-45 years
3. Willing to participate in the clinical study and sign informed consent of meeting the above-mentioned criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

Key exclusion criteria
1. Patient with maxillofacial deformities secondary to cleft lip and palate, tumor, trauma and other congenital factors
2. Patients with syndromes such as hemifacial microsomia, first and second arch syndrome, etc
3. Patients who had undergone previous jaw surgery

Date of first enrolment
20/07/2022

Date of final enrolment
20/01/2024

Locations

Countries of recruitment
China

Study participating centre
West China Hospital of Stomatology, Sichuan University
No. 14, Section 3
Ren Min Nan Road
Chengdu
China
610041

Study participating centre
Hospital of Stomatology, Jilin University
1500 Qinghua Road
Chaoyang District
Changchun
China
130021

Study participating centre
Shenzhen University Affiliated Shenzhen Stomatological Hospital
No. 1098, Xueyuan Avenue, Xili University Town
Shenzhen
China
518055

Sponsor information

Organisation
West China Hospital of Stomatology, Sichuan University

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
West China Hospital of Stomatology, Sichuan University

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	Primary outcome measure		26/06/2024	No	No
Dataset	Primary outcome measure		26/06/2024	No	No
Participant information sheet	version 3		31/05/2022	No	Yes
Participant information sheet	version 3		31/05/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			31/05/2022	No	No
Statistical Analysis Plan			06/06/2024	No	No