Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial comparing the effect of conventional method and method of use three-dimensional printers on the reconstruction difficulties of the mandibular body during surgery and afterwards

Protocol summary

Summary

20 adult patients, regardless of sex and age limits, from the patients referred to the department of oral and maxillofacial surgery of Yazd are selected. All of them must have benign pathological lesion (ameloblastoma, odontogenic keratocyst, etc) involving only mandibular body (from distal aspect of canine tooth to mandibular angle) unilaterally , requiring resection and subsequent reconstruction of the body of mandible under general anesthesia. Patients are randomly divided into two groups. They will be ready for operation, one group using conventional methods and the other using three-dimensional printing technology. In the group using three-dimensional printer, after acquiring a CT scan of axial, coronal and three-dimensional reconstruction views, prototype three-dimensional models of the patient's facial bones are fabricated. Then, while studying the three-dimensional model, required treatment plan is determined and shaping and adapting reconstruction plates on the model, which represents the state of the mandibular bone lesion morphology is done. The pre-shaped and adapted reconstruction plates will be delivered to hospital’s CSR for sterilization. In the group using conventional method, CT Scan of axial, coronal and three-dimensional reconstruction views are provided for patients but required treatment plan is determined using only clinical assessment and radiographic evaluation and three-dimensional models will not be manufactured. After routine tests surgery is performed. The amount of mouth opening will be measured in both groups before surgery. In the intervention group, during surgery, after resection of bone lesions, pre-shaped plates are placed at the site of reconstruction; while in the control group reconstruction plates are shaped routinely during the surgery and adapted on the bone. Finally, after placement and fixation of reconstruction plates, surgical site will be sutured to end the surgery. During surgery, the amount of blood loss and duration of the operation is measured in both groups. After surgery, mouth opening and post-operative pain is evaluated in multiple time periods. Also the risk of plate exposure and infection during six months of follow-up will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605073398N4**
Registration date: **2016-05-20, 1395/02/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-20, 1395/02/31

Registrant information

Name

Alireza Navabazam

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 353624760

Email address

navabazam@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoghi University Of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date
2015-09-23, 1394/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial comparing the effect of conventional method and method of use three-dimensional printers on the reconstruction difficulties of the mandibular body during surgery and afterwards

Public title
Compare the conventional method and the method of using three-dimensional printers in reconstruction of the mandibular body and Determine the effect of these methods on Intraoperative and postoperative problems
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: They all have a benign pathological lesion that only involve unilateral body of the mandible (the distal of canine tooth to the angle of mandible) and require resection and subsequent reconstruction surgical procedure under general anesthesia Exclusion criteria: Systemic problems; kidney defects; neurological and psychological problems; diabetes; hypertension; pregnancy; coagulation problems; use of bisphosphonates; the broad-spectrum antibiotics; corticosteroids and non-steroidal analgesics
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoghi University of Medical Sciences
Street address
Shahid Sadoghi University of Medical Sciences, Western Sadoughi Blvd, Bahonar Square
City
Yazd
Postal code
Approval date
2016-05-09, 1395/02/20
Ethics committee reference number
IR.SSU.REC.1395.20

Health conditions studied

1

Description of health condition studied
pathologic lesion of mandibular body
ICD-10 code
D 16.5
ICD-10 code description
Benign neoplasm of bone and articular cartilage

Primary outcomes

1

Description
surgery duration
Timepoint
from preparation of patient until extubation
Method of measurement
Questionnaire

2

Description
pain
Timepoint
2،6،12،24،48،72 hours after surgery
Method of measurement
Questionnaire

3

Description
duration of resection of bone and reconstruction of mandible
Timepoint
The onset of bone resection to close the last screw on the reconstruction plate
Method of measurement
Questionnaire

4

Description
blood loss

Timepoint
Intraoperative
Method of measurement
Questionnaire

5

Description
mouth opening
Timepoint
before surgery,24,48,72 and a week after surgery
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
intervention1: In the group using three-dimensional printer, after acquiring a CT scan of axial, coronal and three-dimensional reconstruction views, prototype three-dimensional models of the patient's facial bones are fabricated. Then, while studying the three-dimensional model, required treatment plan is determined and shaping and adapting reconstruction plates on the model, which represents the state of the mandibular bone lesion morphology is done. The pre-shaped and adapted reconstruction plates will be delivered to hospital’s CSR for sterilization. After routine tests surgery is performed. The amount of mouth opening will be measured before surgery. during surgery, after resection of bone lesions, pre-shaped plates are placed at the site of reconstruction; Finally, after placement and fixation of reconstruction plates, surgical site will be sutured to end the surgery. During surgery, the amount of blood loss and duration of the operation is measured in both groups. After surgery, mouth opening and post-operative pain is evaluated in multiple time periods. Also the risk of plate exposure and infection during six months of follow-up will be examined.
Category
Treatment - Surgery

2

Description
intervention2l: In the group using conventional method, CT Scan of axial, coronal and three-dimensional reconstruction views are provided for patients but required treatment plan is determined using only clinical assessment and radiographic evaluation and three-dimensional models will not be manufactured. After routine tests surgery is performed. The amount of mouth opening will be measured before surgery. reconstruction plates are shaped routinely during the surgery and adapted on the bone. Finally, after placement and fixation of reconstruction plates, surgical site will be sutured to end the surgery. During surgery, the amount of blood loss and duration of the operation is measured. After surgery, mouth opening and post-operative pain is evaluated in multiple time periods. Also the risk of plate exposure and infection during six months of follow-up will be examined.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Department Of Oral and Maxillofacial Surgery, Faculty Of Dentistry
Full name of responsible person
Dr Mohammad Mahdi Nasiri
Street address
Department Of Oral and Maxillofacial Surgery, Faculty Of Dentistry
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shahid Sadoghi University of Medical Sciences
Full name of responsible person
Dr Amir Hoshang Mehrparvar
Street address
Third Floor, Shahid Sadoghi University of Medical Sciences, Bahonar Square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Shahid Sadoghi University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Sadoghi University Of Medical Sciences
Full name of responsible person
Dr Mohammad Mahdi Nasiri
Position
Resident Of Oral & Maxillofacial Surgery
Other areas of specialty/work
Street address
Dental School, At the beginning of the Dahe Fajr Street, Emam Khomeini Blvd
City
Yazd
Postal code
Phone
+98 35 3625 8881
Fax
+98 35 3625 0344
Email
mohamadmahdi.nasiri@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Sadoghi University Of Medical Sciences
Full name of responsible person
Dr Alireza Navabazam
Position
Maxillofacial Surgeon
Other areas of specialty/work
Street address
Dental School, At the beginning of the Dahe Fajr Street, Emam Khomeini Blvd
City
Yazd
Postal code
Phone
+98 35 3625 8881
Fax
+98 35 3625 0344
Email
navabazam@ssu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Sadoghi University Of Medical Sciences
Full name of responsible person
Dr Mohammad Mahdi Nasiri
Position
Resident Of Oral & Maxillofacial Surgery
Other areas of specialty/work
Street address
Dental School, At the beginning of the Dahe Fajr Street, Emam Khomeini Blvd
City
Yazd
Postal code
Phone
+98 35 3625 8881
Fax
+98 35 3625 0344
Email
mohamadmahdi.nasiri@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty