

**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**

Release Date: May 15, 2020

**ClinicalTrials.gov ID: NCT04396054**

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### Study Identification

Unique Protocol ID: UAlexandriaDentSurg1

Brief Title: Comparison of Double Y-shaped Plates and Lag Screws in Fixation of Anterior Mandibular Fractures

Official Title: Comparison of Double Y-shaped Plates and Lag Screws in Fixation of Anterior Mandibular Fractures

Secondary IDs:

### Study Status

Record Verification: May 2020

Overall Status: Completed

Study Start: September 3, 2019 [Actual]

Primary Completion: February 20, 2020 [Actual]

Study Completion: February 20, 2020 [Actual]

### Sponsor/Collaborators

Sponsor: Lydia Nabil

Responsible Party: Sponsor-Investigator

Investigator: Lydia Nabil [lydianabil]

Official Title: Assistant Professor of Oral and Maxillofacial Surgery

Affiliation: University of Alexandria

Collaborators:

### Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: IRB 00010556-IORG 0008839

Board Name: Research Ethics Committee-Alexandria Faculty of Dentistry

Board Affiliation: Faculty of Dentistry, Alexandria University, Egypt

Phone: 4812201

Email: dent-dean@alexu.edu.eg

Address:

Champion Street  
Azarita, Alexandria, Egypt

Data Monitoring: No  
FDA Regulated Intervention: No

## Study Description

**Brief Summary:** This study is a prospective randomized controlled clinical trial. It was performed on sixteen patients with anterior mandibular fractures, to compare Double Y-shaped plates and Lag Screws in fracture fixation from clinical and radiographic perspectives.

**Detailed Description:** This study is a prospective randomized controlled clinical trial. It was performed on sixteen patients with anterior mandibular fractures, selected from those admitted to the Emergency Department of Alexandria University Hospital. Ethical approval for the study was obtained from the regional Ethical Review Board of the Faculty of Dentistry, Alexandria University. A written informed consent was signed by patients before the operation.

Patients were divided equally into two groups, each consisting of eight patients. Assignment of each patient into one of either group was done using computer random numbers.

Group 1: underwent open reduction and internal fixation using two lag screws.  
Group 2: underwent open reduction and internal fixation using double Y-shaped plates.

## Conditions

**Conditions:** Mandibular Fractures

**Keywords:**

## Study Design

**Study Type:** Interventional

**Primary Purpose:** Treatment

**Study Phase:** N/A

**Interventional Study Model:** Parallel Assignment

**Number of Arms:** 2

**Masking:** Single (Participant)

**Allocation:** Randomized

**Enrollment:** 16 [Actual]

## Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Lag Screws Group 1: underwent open reduction and internal fixation using two lag screws.	Device: Lag Screws Method of internal fixation
Active Comparator: Double Y-shaped plates	Device: double Y-shaped plates Method of internal fixation

Arms	Assigned Interventions
Group 2: underwent open reduction and internal fixation using double Y-shaped plates.	

## Outcome Measures

Primary Outcome Measure:

1. progress of fracture healing in the postoperative period  
Measurement of bone density in the fracture line using CBCT at 6 points and calculation of mean bone density  
[Time Frame: after 6 months]
2. Sensory nerve function using dental probe to assess sensory changes along mental nerve distribution and comparing it to the contralateral side  
Detection of nerve injury by examining sensory nerve function using dental probe to assess sensory changes along mental nerve distribution and comparing it to the contralateral side  
[Time Frame: up to 6 months]

## Eligibility

Minimum Age: 25 Years

Maximum Age: 45 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients of both genders
- with age ranging from 25 to 45 years,
- suffering from anterior fractures of the mandible (symphyseal or parasymphyseal)

Exclusion Criteria:

- old fractures,
- infected fractures
- comminuted fractures

## Contacts/Locations

Central Contact Person: Lydia Melek, PhD  
Telephone: 01224807468  
Email: lydia.nabil@dent.alex.edu.eg

Central Contact Backup:

Study Officials:

Locations: **Egypt**  
Faculty of Dentistry  
Alexandria, Egypt, 21411  
Contact: Lydia Melek 01224807468

**IPDSharing**

Plan to Share IPD: No

**References**

Citations:

Links:

Available IPD/Information: