Risk Factors for Post-Operative Nonunion of Tibial Shaft Fractures Based on a Path Analysis Model

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NCT03928912	COMPLETED	APRIL 26, 2019	APRIL 26, 2019

STUDY DESCRIPTION

Brief Summary

Tibial shaft fractures is common long tubular fracture that account for about 13.7% of all fractures. And the incidence of nonunion of tibial shaft fracture varied from 1% to 80%. This study aimed to confirm the risk factors of nonunion of tibial shaft fracture. Moreover, the investigators hope to establish the clinical pathway of various risk factors for fracture nonunion and affirm the importance of different risk factors.

Condition or Disease: Nonunion of Fracture of Tibia (Diagnosis)

Intervention/treatment:

Phase: N/A

DETAILED DESCRIPTION

Tibial shaft fractures is common long tubular fracture that account for about 13.7% of all fractures. And the incidence of nonunion of tibial shaft fracture varied from 1% to 80%. The investigators retrospectively analyzed the demographics of these participants in our hospital that occur long tubular fracture. One group is participants that existed fracture nonunion. And the other group is the participants that did not exist fracture nonunion. The investigators recorded twelve variables and confirm the risk factors by uni-variate Logistic regression analysis. Moreover, the investigators hope to establish the clinical pathway of various risk factors for fracture nonunion and affirm the importance of different risk factors.

STUDY DESIGN

Study Type: Observational

Estimated Enrollment : 234 participants

Intervention Model : N/A

Masking: N/A

Primary Purpose: N/A

Official Title: Risk Factors for Post-Operative Nonunion of Tibial Shaft Fractures Based on a Path Analysis Model: A Case-Control Study

Actual Study Start Date: February 2019

Actual Primary Completion Date: April 2019

Actual Study Completion Date: April 2019

OUTCOME MEASURES

Primary Outcome Measures: 1. the Gustilo type of the open fracture [Time Frame: the outcome of the Gustilo type can acquire within 1 week.]
the Gustilo type of the open fracture can be divided into three types. And the type I is the open fractures with wounds that is clean and smaller than 1cm. Type II is the the open fractures with wounds that is moderately unclean and bigger than 1cm, which also has a wide soft tissue injury. Type III is the all open fractures that accompany with severe soft tissue injury and pollution.

ELIGIBILITY CRITERIA

Ages Eligible for Study: (Child, Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- The tibial shaft fracture was caused by trauma.

Exclusion Criteria:
- The tibial shaft fracture was caused by tumor, infection and other reasons.

CONTACTS AND LOCATIONS

Contacts

Locations

China, Zhejiang | Institutional Review Board of The Second Affiliated Hospital of Zhejiang University School of Medicine | Hangzhou

Sponsors and Collaborators

Second Affiliated Hospital, School of Medicine, Zhejiang University

Investigator

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MORE INFORMATION

Responsible Party :	Second Affiliated Hospital, School of Medicine, Zhejiang University
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Studies a U.S. FDA-regulated Device Product:	No
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Additional relevant MeSH terms :	*Fractures, Bone* *Tibial Fractures* *Fractures, Ununited*