Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation and comparison the complications and cure of open fracture of Tibia anti-biotic treatment with debridement and additional ozone therapy by clinical trial study design

Protocol summary

Summary

The aim of this study was to determine the effects of adding ozone therapy in the treatment of open fractures can be treated with antibiotics. All patients with tibial shaft open fractures type IIIa gustilo anderson classification are enrolled. Debridement, temporary fixation and antibiotic therapy include Cefazolin 2g every 6 hours and gentamicin 80 mg every 12 hours is done in first 8 hours. After 48 hours wound closure and fixation is performed for patients and who do not have clean wound or have contraindications to ozone therapy, are not enrolled. The sample size is 100. Patients were randomly divided into two groups. The first group only underwent surgical debridement and antibiotic treatment practices are above. In addition to these treatments for group II, ozone therapy is done as placing the limb in a plastic bag for 30-20 minutes at a concentration of 5-6 mg / l and minor autohemotherapy on a daily basis for 7 days. For the first group of patients to eliminate the psychological effects of received additional treatment, a similar way to ozone therapy but totally ineffective is performed using air. Patients is seen with orthopedic researcher who is unaware of the division of patients two weeks after surgery and then monthly for 12 months after stabilization surgery. Signs of infection, healing, union, Knee Score and Ankle Score are recorded at each visit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012511898N9**
Registration date: **2014-02-05, 1392/11/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-02-05, 1392/11/16

Registrant information

Name
Ahmadreza Mirbolouk
Name of organization / entity
Guilin University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 13 1322 2250
Email address
ah.mirbolouk@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Guilan University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-09-22, 1393/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison the complications and cure of open fracture of Tibia anti-biotic treatment with debridement and additional ozone therapy by clinical trial study design

Public title

Therapeutic effect of ozone therapy on open fracture

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: open fracture of tibia shaft, type IIIa gustilo anderson classification Exclusion criteria: 1-not having clean wound in firs 48 hour 2-contraindications of ozone therapy including coagulation disorders, organ's bleeding, allergies to ozone or ozone intolerance, hemorrhagic or apoplectic stroke, G6PD deficiency and interaction with anticoagulants
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences
Street address
Gas field, Ethics Committee of Guilan University of Medical Sciences
City
Rasht
Postal code
41938-93345
Approval date
2013-10-05, 1392/07/13
Ethics committee reference number
1920251610

Health conditions studied

1

Description of health condition studied
open fracture of Tibial shaft
ICD-10 code
S82.2
ICD-10 code description
With or without mention of fracture of fibula

Primary outcomes

1

Description
Union of the fracture
Timepoint
First 2 weeks and then monthly until 12 months after permanent fixation
Method of measurement
AP and lateral radiography

Secondary outcomes

1

Description
Infection of wound
Timepoint
First 2 weeks and then monthly until 12 months after permanent fixation
Method of measurement
Localized and systemic signs of infection, lab data include CBC, Diff, ESR and CRP and wound biopsy and calture

2

Description
Recovery time
Timepoint
First 2 weeks and then monthly until 12 months after permanent fixation
Method of measurement
Union without infection in AP and lateral radiography

3

Description
Knee Score
Timepoint
Measured on admission and 6 and 12 months later
Method of measurement
Knee Score questionnaire

4

Description
Ankle Score
Timepoint
Measured on admission and 6 and 12 months later
Method of measurement
Ankle Score questionnaire

Intervention groups

1

Description
Debridement, Antibiotic therapy include Cefazolin 2g every 6 hours and gentamicin 80 mg every 12 hours is done in first 8 hours and similar way to ozone therapy include placing the limb in a plastic bag for 30-20 minutes at a concentration of 5-6 mg / l and minor autohemotherapy on a daily basis for 7 days with air for group 1 (control)

Category
Treatment - Other

2

Description
Debridement, Antibiotic therapy include Cefazolin 2g every 6 hours and gentamicin 80 mg every 12 hours is done in first 8 hours and ozone therapy include placing the limb in a plastic bag for 30-20 minutes at a concentration of 5-6 mg / l and minor autohemotherapy on a daily basis for 7 days with ozone for group 2 (intervention)

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Poursina hospital, Guilan University of Medical Sciences

Full name of responsible person
Maral Farahmand

Street address

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Guilan University of Medical Sciences

Full name of responsible person
Dr. Abtin Heidarzadeh - Research deputy of Guilan university of medical sciences

Street address
Gas field, Vice Chancellor for Research Guilan University of Medical Sciences

City
Rasht

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, Guilan 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
Guilan University of medical sciences

Full name of responsible person
Maral Farahmand

Position
Medical student

Other areas of specialty/work

Street address
Poursina hospital - Orthopaedic Research Center

City
Rasht

Postal code

Phone
+98 13 1322 3970

Fax

Email
maral.farahmand@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Guilan University of medical sciences

Full name of responsible person
Dr. Ahmadreza Mirbolook

Position
Specialist in Orthopedic Surgery

Other areas of specialty/work

Street address
Poursina hospital - Orthopaedic Research Center

City
Rasht

Postal code

Phone
+98 13 1322 3970

Fax

Email
ahmadreza_mirbolook@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Guilan University of medical sciences

Full name of responsible person
Maral Farahmand

Position
Medical student

Other areas of specialty/work

Street address
Poursina hospital - Orthopaedic Research Center

City
Rasht

Postal code

Phone
+98 13 1322 3970

Fax

Email
maral.farahmand@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