

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation the effect of ozone therapy in the treatment of patients with chronic osteomyelitis in orthopedic clinic of PourSina'hospital

Protocol summary

Summary

In orthopedic surgery, osteomyelitis is a rare complication, but annoyingly hard to antibiotic treatment. FDA recently approved for Ozone treatment of osteomyelitis (that resistant to antibiotics). In this study, patients were divided to two groups: 1) treatment with antibiotics, 2) antibiotics and ozone therapy. Redness, swelling, increased ESR and CRP, suspect to osteomyelitis. Bone biopsy and bone culture is used. People with bleeding disorders, those with bleeding organs, people who have allergies or are not tolerate Ozone, Patients with hemorrhagic stroke or Apoplectic, enzyme deficiency G6PD, interact with anticoagulants and those who are in mense period, are excluded in the treatment of. The aim of this study was to determine the effect of Ozone therapy in the treatment of osteomyelitis with antibiotics versus antibiotics alone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306276186N2**

Registration date: **2013-08-26, 1392/06/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-26, 1392/06/04

Registrant information

Name

Bahram Naderi Nabi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3323 4600

Email address

naderi_bahram@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2013-04-22, 1392/02/02

Expected recruitment end date

2013-08-24, 1392/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of ozone therapy in the treatment of patients with chronic osteomyelitis in orthopedic clinic of PourSina'hospital

Public title

effect of ozone therapy on the treatment of patients with chronic osteomyelitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: patients with redness and swelling action and increased ESR and CRP ; a bone biopsy involved and culture is positive. Exclusion criteria: people with bleeding disorders, those with bleeding organs; people who are allergic to ozone or can not tolerate it; those with hemorrhagic stroke or Apoplectic; deficiency of the enzyme G6PD; interact with anticoagulants and those who are in mense.

Age

From **14 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Guilan University of Medical Sciences

Street address

Azodi street

City

Rasht

Postal code

4193833697

Approval date

2013-04-20, 1392/01/31

Ethics committee reference number

1920029701

Health conditions studied**1****Description of health condition studied**

chronic osteomyelitis

ICD-10 code

M86.3

ICD-10 code description

Chronic multifocal osteomyelitis

Primary outcomes**1****Description**

ESR

Timepoint

Before surgery and weekly

Method of measurement

Westergren method, mm/h

2**Description**

CRP

Timepoint

Before surgery, then weekly

Method of measurement

Latex agglutination / titration

3**Description**

The position involves the disappearance of clinical symptoms

Timepoint

Treatment

Method of measurement

Visual

4**Description**

Lesion culture

Timepoint

Debridment time

Method of measurement

In chocolate agar & mac cankey

Secondary outcomes**1****Description**

Purulent discharge

Timepoint

Debridment time

Method of measurement

visual

Intervention groups**1****Description**

Antibiotic & Ozone thrapy, Ozone 35%, 0.3 micrograms per kg weight every other day

Category

Treatment - Other

2**Description**

Antibiotics for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pain Clinic of Poursina Hospital

Full name of responsible person

Bahram Naderi

Street address

Parastar street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor, Management & Resource development
Guilan University of Medical Sciences

Full name of responsible person

abdolrasool sobhani

Street address

Emam khomeiny Blv. top of the IRAN Radiator CO.

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, Management & Resource development
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

Bahram Naderi Nabi

Position

FIPP/assistant professor

Other areas of specialty/work**Street address**

Pain clinic of Poursina Hospital

City

Rasht

Postal code

41937-13194

Phone

+98 13 1321 0434

Fax

+98 13 1323 9843

Email

naderi_baghram@gums.ac.ir; ARC@gums.ac.ir;
vbuh.research@gmail.com

Web page address

www.gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Bahram Naderi

Position

FIPP/Assistant professor

Other areas of specialty/work**Street address**

Poursina Hospital

City

Rasht

Postal code

41937-13194

Phone

+98 13 1321 0434

Fax

+98 13 1324 5132

Email

naderi_bahram@gums.ac.ir; ARC@gums.ac.ir;
vbuh.research@gmail.com

Web page address

www.gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Hedieh Nemati

Position

BA / medical lab sciences

Other areas of specialty/work**Street address**

Poursina Hospital

City

Rasht

Postal code

41937-13194

Phone

+98 13 1321 0434

Fax

+98 13 1323 9842

Email

naderi_bahram@gums.ac.ir; ARC@gums.ac.ir;
vbuh.research@gmail.com; h_n_112@gmail.com

Web page address

www.gums.ac.ir

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