

# 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*