

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

comparing the effectiveness of combined hyperthermia and external beam radiotherapy versus EBRT alone in treating patients with painful bone metastases

Protocol summary

Study aim

Comparison of the effect of radiotherapy and hyperthermia with radiotherapy alone in the treatment of bone metastases

Design

In this study, an intervention, conducted as a randomized clinical trial, will comprise patients with bone metastases of the community under study.

Settings and conduct

Firoozgar Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age less than 80 "Patient performance status based on ECOG less than 3" Life expectancy over 3 months Patients who have cardiac pacemakers "and those who have radiotherapy in or out of the body for any metal reason. Neuropathy for any reason that has caused pain sensation

Intervention groups

Bone metastasis

Main outcome variables

Reduce pain

General information

Reason for update

Acronym

hyperthermia

IRCT registration information

IRCT registration number: **IRCT20170306032913N3**

Registration date: **2020-02-04, 1398/11/15**

Registration timing: **retrospective**

Last update: **2020-02-04, 1398/11/15**

Update count: **0**

Registration date

2020-02-04, 1398/11/15

Registrant information

Name

Alireza Nikoofar

Name of organization / entity

Firoozgar Clinical Research Development Center (FCRDC)

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1743

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-30, 1396/11/10

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

2018-01-30, 1396/11/10

Actual recruitment end date

2019-03-01, 1397/12/10

Trial completion date

2019-03-01, 1397/12/10

Scientific title

comparing the effectiveness of combined hyperthermia and external beam radiotherapy versus EBRT alone in treating patients with painful bone metastases

Public title

comparing the effectiveness of combined hyperthermia and external beam radiotherapy versus EBRT alone in treating patients with painful bone metastases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age less than 80 Patient performance status based on ECOG less than 3 Life expectancy exceeds 3 months

Exclusion criteria:**Age**

From **80 years** old to **80 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

IUMS

Street address

Tehran Hemat Highway next to Milad Tower 14496.
14535

City

Teran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-01-30, 1396/11/10

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411188002

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

age

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

sex

Timepoint

-

Method of measurement

questionnaire

Secondary outcomes

empty

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

Intervention group: 1

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firoozgar Hospital & Clinic

Full name of responsible person

alireza nikoofar

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خیابان شهید ولدی

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Email

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

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h_firoozgar@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
30
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
alireza nikoofar
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available