Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
nikoofar@iums.ac.ir

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
Street address
خیابان شهید ولدی
City
tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1201
Fax
+98 21 8214 1201
Email
arnikoofar@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
alireza nikoofar
Street address
shahid valadi
City
tehran
Province

Tehran
Postal code
1593747811
Phone
+98 21 8214 1201
Fax
+98 21 8214 1201
Email
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
Radiotherapy
Street address
shahid valadi
City
tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1201
Fax
+98 21 8214 1321
Email
arnikoofar@gmail.com
Web page address
https://firoozgar.iums.ac.ir/

Person responsible for scientific 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
Radiotherapy
Street address
shahid valadi
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1321
Fax
+98 21 8214 1321
Email
arnikoofar@gmail.com
Web page address
https://firoozgar.iums.ac.ir/

Person responsible for updating data

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
Radiotherapy
Street address
shahid valadi
City
tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1321
Fax
+98 21 8214 1321
Email
arnikoofar@gmail.com
Web page address
https://firoozgar.iums.ac.ir/

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