Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

Evaluation of low dose radiotherapy on hypophyses in multiple sclerosis patients

Protocol summary

Study aim
Evaluation of low dose radiotherapy of hypophysis on disease improvement among Multiple sclerosis patients.
Design
Ten Multiple sclerosis patients, enlisted in Kerman MS society, with disability score of more than 6 were selected. Each patient received radiotherapy by a linear accelerator for 5 sessions, 2 Gray per session, 10 Gray overall.
Settings and conduct
At the Radiotherapy ward of Shafa Medical Center, affiliated to Kerman University of Medical Sciences.
Participants/Inclusion and exclusion criteria
Multiple sclerosis patients
Intervention groups
Multiple sclerosis patients with pituitary height greater than 5.7 mm received radiotherapy for pituitary gland at the dose of 2 Gray daily for 5 consecutive days using linear accelerator.
Main outcome variables
early fatigue

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20111217008436N4**
Registration date: **2018-03-01, 1396/12/10**
Registration timing: **prospective**

Last update: **2018-03-01, 1396/12/10**
Update count: **0**
Registration date
2018-03-01, 1396/12/10

Registrant information
Name
Hossein Ali Ebrahimi
Name of organization / entity
Neurology Research Center
Country
Iran (Islamic Republic of)
Phone
+98 34 1246 7500
Email address
hebrahimi@kmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-21, 1397/02/01
Expected recruitment end date
2020-04-20, 1399/02/01
Actual recruitment start date
2018-04-21, 1397/02/01
Actual recruitment end date
2020-04-20, 1399/02/01
Trial completion date
empty

Scientific title
Evaluation of low dose radiotherapy on hypophyses in multiple sclerosis patients

Public title
Radiotherapy in Multiple sclerosis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Multiple sclerosis patients Filling the informed consent The rate of EDSS above 6 (Kurtzke scale) The height of hypophysis more than 5.7 mm
Exclusion criteria:
Uncorporation Low conciousness Other disorder
Age
No age limit

Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **10**
Actual sample size reached: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Nothing: don't blinded

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Deputy of research Kerman University of Medical Sciences, Somaeh cross, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7618759684
Approval date
2017-12-16, 1396/09/25
Ethics committee reference number
IR.KMU.REC.1396.1920

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Early fatigue
Timepoint
first, second, third, and sixth month
Method of measurement
Expanded disability status scale

2

Description
The rate of new attacks
Timepoint
After 6 months
Method of measurement
Clinical examination

3

Description
New lesions on brain MRI scan
Timepoint
Sixth and 24th month
Method of measurement
Report of Radiologist and comparing with last MRI

Secondary outcomes

empty

Intervention groups

1

Description
Radiotherapy Technique: all the patients will be treated in supine position. Thermoplastic pillows and masks will be used to fix patients. Having placed the required markers, all patients will go through brain CT-Scan imaging at slice thickness of 5 mm. These images will be uploaded to ISOgray treatment planning application for a 3D treatment plan. The treatment field will include the sellar region plus a margin of 1 cm. We will take pains not to involve the cranial nerve and tract, as far as possible. To this end, shield will be applied in special cases. All patients will be treated with lateral and parallel opposite fields, at a daily dose of 2 Gray for 5 consecutive days, totally 10 Gray. A 6-MV linear accelerator will be used for the treatment.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Medical Center

Full name of responsible person
Mohammad Hasan Lari Zadeh M.D
Street address
Shafa Hospital, Shafa avenue, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7618751151
Phone
+98 34 3211 5810
Fax
+98 34 3212 4727
Email
kmu.nrc@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Gholam Reza Sepehri PhD
Street address
Vice chancellor for research, Kerman University of Medical Sciences, Somayyeh crossroad, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3855
Fax
Email
kmu.nrc@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
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
Kerman University of Medical Sciences
Full name of responsible person
Hossein Ali Ebrahimi Meimand M.D
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Neurology Research Center, No 1, 22 Shafa avenue
Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7618751151
Phone
+98 34321224727
Fax
+98 34 3212 4727
Email
kmu.nrc@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hossein Ali Ebrahimi Meimand M.D
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Neurology Research Center - No 1 - 22 Shafa avenue
City
Kerman
Province
Kerman
Postal code
7618751151
Phone
+98 34 3232 4727
Email
kmu.nrc@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hossein ali Ebrahimi Meimand
Position
professor

Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Neurology Research Center - No 1 -22 Shafa avenue - Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7618751151
Phone
+98 34 3212 4727
Email
kmu.nrc@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It includes the patients information and the information should be kept secret
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
rate of received Radiation dose in patients; cure rate (Fatigue, EDSS); Side effects and reasons of the patients incorporation
When the data will become available and for how long
The first report will be released after 3 months The final report will be released after 2 years
To whom data/document is available
All of Neurologist and Neurosciences researchers: Academic and Medical
Under which criteria data/document could be used
The researchers who identified by Kerman university of Medical Sciences
From where data/document is obtainable
Neurology Research Center - Kerman University of Medical Sciences
What processes are involved for a request to access data/document
After receiving the request by NRC (Neurology Research Center), the other process will be done by NRC.
Comments