

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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