

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Radiologic response evaluation after conventional whole brain radiation therapy plus concurrent oral administration of losartan versus radiation therapy alone in patients with brain metastasis

Protocol summary

Study aim

Evaluation radiologic response to whole brain radiotherapy with administration concurrent oral losartan versus radiotherapy alone in brain metastasis

Design

Clinical trial with controlled group, with parallel group, double blinded, randomised

Settings and conduct

Patients with brain metastasis attending in radiotherapy ward of Ahvaz Golestan hospital and with eligible criteria divided into two groups. Intervention group will receive the standard whole brain radiotherapy and oral Losartan, whereas the control group will be treated with standard whole brain radiotherapy and placebo. Participant and researcher are unaware which group receives drug, and which group receives the placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients with a pathology confirmed extracranial malignancy & MRI suggest brain metastasis. Exclusion criteria included the lack of history of previous brain radiotherapy or radiosurgery & no previous treatment with angiotensin converting enzyme inhibitors and angiotensin receptor blockers.

Intervention groups

Intervention group will receive 30 Gray in 10 fractions whole brain radiotherapy and 25 milligram Losartan as a radiosensitizer during radiation course. The control group will receive the same radiation dose and placebo.

Main outcome variables

Radiologic response of brain lesions to radiation with adding Losartan as a radiosensitizer will be investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170314033080N2**

Registration date: **2018-03-11, 1396/12/20**

Registration timing: **prospective**

Last update: **2018-03-11, 1396/12/20**

Update count: **0**

Registration date

2018-03-11, 1396/12/20

Registrant information

Name

Yasamin Mahouram

Name of organization / entity

Ahvaz Jundishapour University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 3321 9277

Email address

mahouram.y@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

no charge from any institute

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radiologic response evaluation after conventional whole

brain radiation therapy plus concurrent oral administration of losartan versus radiation therapy alone in patients with brain metastasis	
Public title	Effect of losartan with whole brain radiotherapy in brain metastasis
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Extracranial metastasis confirmed by pathology MRI imaging suggestive for brain metastases with at least 1 cm in size Predicted survival at least 8 weeks for patient Zubrud performance scale 0, 1, 2, 3 Absolut neutrophil count>1000 in mm ³ Serum platlet >50000 in mm ³ Serum Creatinin< 1.5 mg/d BUN<25 in dl Serum potassium 3.5-5 mmol/L Get informed consent Exclusion criteria: Sever mental or physical illness disturbing treatment according protocole Previous brain radiotherapy or radiosurgery Patients without regular follow-up Age<18 &>90 years Previous treatment with ACEI/ARB drugs Pregnancy Baseline hypotension Leptomeningeal involvement
Age	From 18 years old to 90 years old
Gender	Both
Phase	2
Groups that have been masked	- Participant - Investigator - Outcome assessor
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Individuals randomly divided to two groups based on fourth permutation blocks, so that researcher do not interfere with the allocation of treatment methods to patients.
Blinding (investigator's opinion)	Double blinded
Blinding description	Participants in study which are patients with brain metastasis, after being informed about attending in a clinical study and obtaining consent, are unaware that they are taking Losartan pill in addition to standard radiotherapy or placebo. The researcher and the evaluator of outcome is also unaware which groups is taking drug and which group taking placebo.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics committee of Ahvaz Jundi shapour University of Medical sciences Street address Golestan, Ahvaz City Ahvaz Province Khuzestan Postal code 6136964695 Approval date 2016-11-19, 1395/08/29 Ethics committee reference number IR.AJUMS.REC.1395.588
Health conditions studied	1 Description of health condition studied Brain metastasis ICD-10 code C71 ICD-10 code description Malignant neoplasm of brain
Primary outcomes	1 Description Radiologic response of brain metastatic lesion Timepoint 6 weeks after ending of intervention Method of measurement RECIST V1.1criteria for response evaluation in solid tumors
Secondary outcomes	1 Description Radiologic response of non target metastatic brain lesion Timepoint 6 weeks after ending intervention Method of measurement RECIST v 1.1 criteria for response evaluation in solid tumors

Intervention groups

1

Description

Intervention group: whole brain radiation with 30 Gray in 10 fractions and using 25 mg losartan tablet during radiation course

Category

Treatment - Drugs

2

Description

Control group: standard treatment with whole brain radiation with 30 Gray in 10 fractions and using placebo during radiation course

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan hospital

Full name of responsible person

Yasamin Mahouram

Street address

Number 20, Day street, Golestan, Ahvaz

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mahouram.yasamin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundi Shapour university of Medical Science

Full name of responsible person

Dr Behzad Sharif Makhmalzade

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Ahvaz, Golestan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundi Shapour university of Medical Science

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

Ahvaz Jundishapour University Of Medical Science

Full name of responsible person

Yasamin Mahouram

Position

Radiotherapy & Oncology assistant

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Name of organization / entity

Ahvaz Jundishapour University Of Medical Science

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Seyed Mohammad Hosseini

Position

Assistant professor of radiotherapy & oncology

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is 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

Participants' demographic information and informed consent form after unidentifiable individuals, also the study protocol include prescribed radiation dose and drug dose and statistical analysis result will be shared.

When the data will become available and for how long

Start the access period, one year after the result are printed.

To whom data/document is available

Data will be available to researchers at university colleges.

Under which criteria data/document could be used

Unidentifiable individual data and analysis result after confirmation of applicants' membership in academic research center, are presented to them.

From where data/document is obtainable

Applicants can submit a request for access by email at the following email address:

mahouram.yasamin@gmail.com Mobile phone

NO:09166110130 Yasamin mahouram, Golestan

hospital, golestan blvd, Ahvaz

What processes are involved for a request to access data/document

The applicant, after submitting a request for access to any releasable data, must send a confirmation of his membership in one of the academic research center and the organization position. The data will be provided to them within maximum one month of receipt of request.

Comments