

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 receive drug, and which group receive 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 Jundishapur 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 metastasis 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<sup>3</sup> Serum platlet >50000 in mm<sup>3</sup> Serum Cratinin < 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 involment

#### 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 reasercher 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 V1.1 criteria 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

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6136964695

#### Phone

+98 61 3321 9277

#### Email

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

#### Street address

Ahvaz, Golestan

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mahouram.yasamin@gmail.com

### 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

#### Street address

No 20, day street, Golestan, Ahvaz

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ahvaz Jundishapour University Of Medical Science

#### Full name of responsible person

Seyed Mohammad Hosseini

#### Position

Assistant professor of radiotherapy & oncology

#### Latest degree

Specialist

#### Other areas of specialty/work

Radiotherapy

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**Web page address****Person responsible for updating data****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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**Province**

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**Postal code**

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**Phone**

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**Fax****Email**

mahouram.y@ajums.ac.ir

**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 results 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 results after confirmation of applicants' membership in academic research centers, 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 centers and the organization position. The data will be provided to them within maximum one month of receipt of request.

**Comments**