

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Radiologic Response to Conventional Whole Brain Radiation Therapy plus Concurrent Intravenous Infusion of Sodium Nitrite versus Radiation Therapy Alone In Patients with Brain Metastases

Protocol summary

Summary

This randomized, single-blind clinical trial intends to evaluate the radiobiological properties of sodium nitrite as a nitric oxide supply in radiation therapy. Therefore, patients suffered from brain metastasis randomly assign into two intervention groups. In the first intervention group, patients are treated with whole brain radiation therapy (WBRT) alone (30 Gy in 10 fractions using opposed parallel 6MV photon beams). In the second intervention group, patients will receive WBRT as the first group, and concomitant two hour intravenous (IV) infusion of sodium nitrite (267 microgram/kilogram/hour) before each fraction of radiation. For evaluation of the effects of this agent, as a radio sensitizer, and measurement of radiologic response rate, magnetic resonance scans (MRI) (T1 sequence plus IV contrast) of patients, before and one month after completion of treatment will be compared based on the extent of the metastases and according to response evaluation criteria in solid tumors (RECIST v1.1). Then patients will be classified into four groups including complete responders, partial responders, progressive and stable disease. Finally radiologic response rate in the two arms of this trial will be analyzed using statistical tests.

General information

Acronym

NORS - Nitric Oxide as a Radio Sensitizer

IRCT registration information

IRCT registration number: **IRCT2013101515026N1**

Registration date: **2013-10-25, 1392/08/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-25, 1392/08/03

Registrant information

Name

Ali Bagheri

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-10-02, 1392/07/10

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radiologic Response to Conventional Whole Brain Radiation Therapy plus Concurrent Intravenous Infusion of Sodium Nitrite versus Radiation Therapy Alone In Patients with Brain Metastases

Public title

Sodium nitrite radio biological properties as a radio sensitizer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Histopathologically confirmed extra cranial malignancy. 2. At least one brain metastasis \geq 1 cm in size demonstrated on a gadolinium enhanced T1 sequence MRI scan. 3. Patients must have an estimated survival of at least 4 weeks. 4. ECOG performance status of 0-3. Exclusion criteria: 1. Major medical illnesses or psychiatric impairments which, in the investigator's opinion, will prevent completion of the protocol therapy. 2. Previous radiotherapy to the head. 3. Patients who cannot be regularly followed. 4. Leptomeningeal involvement

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical sciences

Street address

Golestan Ave.

City

Ahvaz

Postal code

61357-15794

Approval date

2013-09-29, 1392/07/07

Ethics committee reference number

2295//پ/8/20/س

Health conditions studied

1

Description of health condition studied

Brain metastasis

ICD-10 code

C79.3

ICD-10 code description

Secondary malignant neoplasm of brain and cerebral meninges

Primary outcomes

1

Description

Radiologic response

Timepoint

One month after completion of intervention

Method of measurement

According to response evaluation criteria in solid tumors version 1.1 (RECIST)

Secondary outcomes

empty

Intervention groups

1

Description

Whole brain radiation therapy, both arms of the trial, parallel opposed 6MV photon beams, total dose 30 Gy in 10 fractions, 5 days a week, for 2 weeks

Category

Treatment - Other

2

Description

Sodium nitrite, 2 hour intravenous infusion, 267 microgram per kilogram per hour of 3% solution diluted in half liter of normal saline before each fraction of radiation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital, Radiotherapy & Oncology Center

Full name of responsible person

Seyed Mohammad hosseini, Radiation Oncologist

Street address

Golestan Ave.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical sciences

Full name of responsible person

Mohammad reza abbaspour

Street address

Golestan Ave.

City

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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 Jundishapur University of Medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Position

Resident Physician in Radiation Oncology

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty