Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of atorvastatin effects on plasma MMP 9 concentration in neurosurgical- induced brain injuries after glial tumor resection

Protocol summary

Summary

Randomized double blind placebo control trial. Inclusion criteria: Patients undergone neurosurgery with suggested diagnosis of glial tumor. Exclusion criteria: Atorvastatin contraindications: atorvatatin sensitivity, active hepatic disease, pregnancy and lactation. elevated liver enzymes; serious adverse reaction induced by atorvastatin; severe renal or failure; having infectious disease; use of atorvastatin before the study; pathology report of other type of tumors instead of glioma; serious interaction between patients medication with atorvastatin; MAP< 70 mmHg; Na<130mEq/L; Hematocrit<28%. The main goal of study is the evaluation of atorvastatin effects on plasma MMP 9 concentration in neurosurgical- induced brain injuries after glial tumor resection. These Forty four patients with completion of inclusion and exclusion criteria will be randomly included in one of two groups (atorvastatin or placebo) and will be treated with atorvastatin or placebo in addition to typical therapeutic regimen. Blood samples for detection of MMP-9 plasma concentration will be prepared at beginning of study before surgery, 24 hour and two weeks after the surgery.Plasma MMP9 concentration will assessed by ELISA kit. Karnofsky Performance Scale will assessed before and 2 months after the surgery. At last result will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203039196N1**
Registration date: **2012-03-17, 1390/12/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2012-03-15, 1390/12/25
Expected recruitment end date
2012-09-15, 1391/06/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation of atorvastatin effects on plasma MMP 9 concentration in neurosurgical- induced brain injuries after glial tumor resection

Public title

Atorvastatin neuroprotective effects in glial tumor surgey

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients undergone neurosurgery with suggested diagnosis of glial tumor. Exclusion criteria:

Atorvastatin contraindications: atorvatatin sensitivity, active hepatic disease, pregnancy and lactation. elevated liver enzymes; serious adverse reaction induced by atorvastatin; severe renal or hepatic failure; having infectious disease; use of atorvastatin before the study; pathology report of other type of tumors instead of glioma; serious interaction between patients medication with atorvastatin; MAP< 70 mmHg; Na<130mEq/L; Hematocrit<28%.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Ethics Committee

Street address
Poursina St, Enghelab St.

City
Tehran

Postal code

Approval date
2012-02-26, 1390/12/07

Ethics committee reference number
15799

Health conditions studied

1

Description of health condition studied
Glial tumor

ICD-10 code
C71.9

ICD-10 code description
Malignant neoplasm of brain, Brain, unspecified

Primary outcomes

1

Description
MMP-9

Timepoint
At the beginning of study, before surgery, 24 hour and two weeks after the surgery

Method of measurement
Lab test

2

Description
Karnofsky Performance Scale

Timepoint
Before and 2 months after the surgery

Method of measurement
Karnofsky Performance Scale criteria

Secondary outcomes

empty

Intervention groups

1

Description
In atorvastatin (Intervention) group: Atorvastatin, tablet 40 mg, twice daily, one week before surgery and two weeks after the surgery.

Category
Treatment - Drugs

2

Description
In placebo (Control) group: Placebo of atorvastatin, tablet 40 mg, twice daily, one week before surgery and two weeks after the surgery.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran University of Medical sciences affiliated hospitals

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-Chancellor for Research
Street address
Sixth floor, Tehran University of Medical Sciences, Ghods street, Keshavarz blv.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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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