

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the efficacy of radioactive iodide 125 made in Iran in uveal melanoma

Protocol summary

Summary

Purpose: Determining the Efficacy of radioactive Iodide plaques: Inclusion and exclusion keys: All the patients with uveal melanoma not treatable with Ruthenium plaques will include. All the patients with unwillingness to continuing the project, pregnancy, lactation will be excluded from the study. Sample size: 10-15 consecutive patients. the contribution and its time and consequences: After the diagnosis, the iodide plaque will be implanted under the lesion on sclera as soon as it is made and after the predetermined time will be explanted. Then the patient will be followed up in the following months for evaluating any decreasing in the thickness and resorption of subretinal fluid. The stability of the thickness and/or its decreasing is the main outcome of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091929875N1**

Registration date: **2016-10-05, 1395/07/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-05, 1395/07/14

Registrant information

Name

Fariba Ghassemi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5540 0010

Email address

ghasemi_f@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Atomic energy agency and Tehran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of radioactive iodide 125 made in Iran in uveal melanoma

Public title

Using radioactive iodide 125 in uveal melanoma

Purpose

Treatment

Inclusion/Exclusion criteria

INCLUSION: All the patients with uveal melanoma that are not the candidates for ruthenium plaques and un-acceptation of the enucleation by the patient. **Exclusion:** Unwillingness of the patient for continuing the study, pregnancy and nursing.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences ethics committee

Street address

Number 1 building of Tehran University of Medical Sciences, Keshavarz Boulevard, Qods street

City

Tehran

Postal code

Approval date

2016-06-26, 1395/04/06

Ethics committee reference number

IR.TUMS.REC.1395.2742

Health conditions studied

1

Description of health condition studied

Uveal melanoma

ICD-10 code

C69.3

ICD-10 code description

Choroid

Primary outcomes

1

Description

Decrease in the thickness of tumor

Timepoint

At 4 months

Method of measurement

ultrasound and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

This intervention will be undertaken as implantation of Iodide radioactive plaque under the ocular tumor on sclera, for a measured time, according to the thickness of the tumor. After this period of time, the plaque will be removed and the patient will be followed.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

Fariba Ghassemi

Street address

Farabi Hospital, South Kargar street, Qazvin Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoud Younesian

Street address

Farabi Hospital, South Kargar, Qazvin square

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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fariba Ghassemi

Position

Associate professor- MD

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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