

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### comparison of cabergolin with Sandostatin lar plus cabergolin in size reduction of nonfunctional pituitary adenomas after surgery :an open label clinical trial

#### Protocol summary

##### Study aim

In this Open label RCT study , efficacy of treatment with octreotide LAR plus cabergolin is compared with cabergulin only on tumor volume reduction and other symptom and sing of NFPA

##### Design

Two arm parallel groups randomized clinical trial with control

##### Settings and conduct

Patients with NFPA ,referral to endocrine clinic of Iran & Golestan university and undergo Transsphenoidal surgery , patients will be divided in two groups .Tumor size by measuring the adenoma diameter on MRI and visual field by kinetic perimetry (Goldmann perimetry), hormonal profile will be evaluated before treatment and 6 months after treatment. In the end of study , we will compare tumor size, visual field , hormonal profile before and after treatment between two groups.

##### Participants/Inclusion and exclusion criteria

In this study ,patients with NFPA ,in whom total tumor resection is less than 80% after surgery ,or tumor have been regrowth after surgery ,and their tumor is sstr positive in IHC staining for somatostatin receptor is included .

##### Intervention groups

15 patient will receive cabergolin 3 - 7 mg per week for 6 months.15 patient will receive sandostatin lar 20 mg q 28 day plus cabergolin 3 - 7 mg per week for 6 months.

##### Main outcome variables

Tumor volume reduction after surgery, visual field improvement ,pan hypopituitarism and requirement to resurgery

#### General information

##### Reason for update

##### Acronym

ندارد

##### IRCT registration information

IRCT registration number: **IRCT20171003036521N2**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **prospective**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

##### Registration date

2018-03-12, 1396/12/21

##### Registrant information

###### Name

HAMIDEH AKBARI

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8894 5246

###### Email address

akbari.ha@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

IRAN UNIVERSITY OF MEDICAL SCIENCES INSTITUTE OF ENDOCRINOLOGY AND METABOLISEM GOLESTAN UNIVERSITY OF MEDICAL SCIENCE

##### Expected recruitment start date

2018-04-04, 1397/01/15

##### Expected recruitment end date

2020-04-03, 1399/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

comparison of cabergolin with Sandostatin lar plus cabergolin in size reduction of nonfunctional pituitary adenomas after surgery :an open label clinical trial

## Public title

comparison of cabergolin with Sandostatin lar plus cabergolin in treatment of nonfunctional pituitary adenomas

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with NFPAs that don't cured by surgery and are SSR -R 1-5 positive ,who have less than 80% resection rate after surgery Patient with NFPAs and are SSR -R 1-5 positive ,that patient who have tumor regrowth after surgery Patient with NFPAs and are SSR -R 1-5 positive ,who previously didn't have received radiotherapy Patient with NFPAs and are SSR -R 1-5 positive ,who previously didn't have received medical therapy with dopamine agonists or somatostatin analogues Patient with NFPAs who don't , SSR -R 1-5 positive

### Exclusion criteria:

Patients with NFPAs that have cured by surgery ,who have more than 80% resection rate after surgery Patient with NFPAs and , who have emergency surgical indication Patient with NFPAs , who previously have received radiotherapy Patient with NFPAs who have emergency surgical indication Patient with NFPAs ,who previously have received medical therapy with dopamine agonists or somatostatin analogues

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

Random allocation is not applicable .Patients divided in two groups by physician .

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In the study, participants (patients), don't know which group they have been allocated to, but physician know.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Tehran - Hemmat Highway - next to Milad Tower - Iran University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Approval date

2017-10-10, 1396/07/18

##### Ethics committee reference number

IR.IUMS.REC1396.30249

## Health conditions studied

### 1

#### Description of health condition studied

nonfunctional pituitary adenoma

#### ICD-10 code

D35.2

#### ICD-10 code description

Pituitary gland

## Primary outcomes

### 1

#### Description

Non functional pituitary adenoma size

#### Timepoint

Non functional pituitary adenoma size before and 6 months after treatment

#### Method of measurement

Adenoma size in MRI

## Secondary outcomes

### 1

#### Description

Secondary Hypothyroidism

#### Timepoint

Before and 3 , 6 months after treatment

#### Method of measurement

Measurement OF T3 ,T4, TSH , Blood sample

### 2

#### Description

Adrenal insufficiency

#### Timepoint

Before and 3 , 6 months after treatment

**Method of measurement**

Serum Cortisol level, blood sample

**3**

**Description**

Visual field

**Timepoint**

Before and 6 months after treatment

**Method of measurement**

Primetry

**4**

**Description**

Panhypopituitarism

**Timepoint**

Before and 3 , 6 months after treatment

**Method of measurement**

Pituitary hormonal assessment in blood sample

**5**

**Description**

Hypogonadism

**Timepoint**

Before and 3 , 6 months after treatment

**Method of measurement**

Measurement LH,FSH ,Esradiol in women and LH,FSH,Testosterone in men, Blood sample

**Intervention groups**

**1**

**Description**

Grupe 1 or intervention , will receive sandostatin lar 20 mg q 28 day plus cabergolin 3 – 7 mg per week for 6 months.Cabeergolin frome OSVE company and Sandostatin lar frome NOVARTIS company

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Grupe 2 or control will receive cabergolin 3 – 7 mg per week for 6 months.Cabeergolin frome OSVE company

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Iran University of Medical Sciences ,Institute of Endocrinology and Metabolism

**Full name of responsible person**

Dr Mohammad Ebrahim Khamseh

**Street address**

Number 10 , Firoozeh St ,Vali - asr Sq,Tehran, Iran.

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**Email**

khamseh.m@iums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Golestan University of Medical Sciences ,Sayad Shirazi hospital , Gorgan ,

**Full name of responsible person**

Hamideh Akbari

**Street address**

Sayad shirazi bulvare , Gorgan, Iran

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akbari.ha@iums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Seyed Kazem Malakooti

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Research@iums.ac.ir

**Grant name**

**Grant code / Reference number**

30249

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

Yes

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

60

**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

**2**

**Sponsor**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohamad reza honarvar

**Street address**

Falsafi Educational Campus-Shastkola Road- Gorgan-  
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honarvar@goums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Gorgan University of Medical Sciences

**Proportion provided by this source**

40

**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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Hamideh Akbari

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Person responsible for scientific inquiries**

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Professor

**Latest degree**

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**Other areas of specialty/work**

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**Contact**

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Gorgan University of Medical Sciences

**Full name of responsible person**

Hamideh Akbari

**Position**

Associate professor

**Latest degree**

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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**

-

**When the data will become available and for how long**

-

**To whom data/document is available**

-

**Under which criteria data/document could be used**

-

**From where data/document is obtainable**

-

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

-

**Comments**