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

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Iran (Islamic Republic of)

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+98 21 8894 5246

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Recruitment status
Recruitment complete

Funding source
IRAN UNIVERSITY OF MEDICAL SCIENCES INISTITUE OF ENDOCRIONOLOGY 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

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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 Khamse

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

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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
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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
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
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Hamideh Akbari
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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