# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Cabergoline versus Raloxifen in active acromegaly: A block randomized clinical trial

## Protocol summary

**Summary**

Acromegaly is one of the important endocrine diseases with a prevalence of around 38-80 per million worldwide (1). The disease is caused by growth hormone secreting adenomas in the pituitary or by the secretion of GH from extrapituitary sites. The subject of this trial relates to acromegaly caused by pituitary adenomas. GH secreting adenomas are usually diagnosed in a late stage and are mostly macroadenomas (adenoma>=10 mm), and in addition to symptoms of excess GH, symptoms related to local compression like headache or visual field defects are among the serious manifestations of this disease . In addition to sequelae like diabetes, hypertension, sexual dysfunction, and coarse features due to elevated GH (>2.5), these patients have a shorter life expectancy. Moreover, taking into consideration the size of these adenomas, there is a risk of apoplexy and life threatening sequelae. Thus, giving treatment to control GH levels is of utmost importance. First line therapy in these cases is trans-sphenoidal surgery. Yet given the relative response of these cases to surgery, medical treatment has a very important role in resistant cases and in recurrence of disease. Medical treatment includes dopamine agonists like bromocriptine and cabergoline, octreotide receptor agonists, and GH peripheral receptor blockers, in addition to other therapies suggested by different studies like SERM's (selective estrogen receptor modulators) and estrogen. Radiotherapy is another option recommended in conjunction with surgery. Even with the best equipment and an expert surgeon cure rates for macroadenomas after surgery are only 50% (2). Studies have shown that a re-do surgery in these cases is of no added benefit to patients except in cases of apoplexy or compression of vital organs by the adenoma. So, keeping the disease under control by medications like somatostatin antagonists, GH-receptor blockers or dopamine agonists is very important. Studies show that treatment with estrogen or SERM's results in controlling the symptoms of acromegaly. Taking into consideration the high cost of sandostatin-LAR in Iran, this study tries to compare the effects of oral drugs added to the baseline treatment of sandostatin-LAR, in patients not responding to its minimum dose. And, in case there is a response (defined by normalization of IGF-1 and amelioration of symptoms and patient complaints) a more effective medical treatment plan will be suggested to patients. Interestingly, this is the first study worldwide, to compare the effects of 2 oral medications (raloxifen and cabergoline) when combined with a parenteral treatment. In previous studies the efficacy of combining an oral agent with a parenteral one was investigated. Goals: 1.Therapiotic effectiveness of Caberguline compared with Raloxifen for IGF1 and GH reduction and improvement of metabolic factors in patients with acromegaly who resistant to Sandostatin LAR. Design: This study was an open label,single center,block randomized clinical tial. The patients was devided into two groups(based on block randomization).Tablet Cabergulin and Raloxifen was given to patients in group A and B, repectively (3mg/weekly cabergulin and 60 mg BID Raloxifen) . Inclusion criteria: adults more than 18 year old, active acromegaly Exclusion criteria:Pregnancy or breast feeding, advance hepatic or renal failure,malignancy. Clinical and paraclinical laboratory tests was checked at the start, including: systolic and diastolic blood pressure, weight and height in addition to IGF1,GH,FBS,BUN,Cr. Thereafter drugs was administered to patients for three months. At the end of time, mentioned factors was measured,again. The results was compared and reported, finaly. Interventions: Recommendation of cabergulin tablet 3mg weekly and Raloxifen 60 mg bid. Primary outcome variables:IGF1,GH,FBS,BUN,Cr,Systolic and diastolic blood pressure,BMI

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016041025917N2**

Registration date: **2016-09-14, 1395/06/24**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**
2016-09-14, 1395/06/24

**Registrant information**
**Name**
Mehrnaz Imani
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**Recruitment status**
**Recruitment complete**
**Funding source**
Vice chancellor for research, Iran University of Medical Sciences

**Expected recruitment start date**
2016-09-22, 1395/07/01
**Expected recruitment end date**
2017-03-19, 1395/12/29
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Cabergoline versus Raloxifen in active acromegaly: A block randomized clinical trial

**Public title**
Cabergoline versus Raloxifen effect in acromegaly.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: Age older than 18 years; high IGF-1 for age and sex; being on treatment with Sandostatin-LAR (post pituitary surgery) every 28 days for a minimum duration of 3 months. Exclusion criteria: malignancy; advanced hepatic and renal insufficiency.
**Age**
From **18 years** old to **18 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Iran University of Medical Sciences
**Street address**
Ethics committae, Iran University of Medical Sciences, Hemmat freeway,Tehran, Iran
**City**
Tehran
**Postal code**
**Approval date**
2016-08-13, 1395/05/23
**Ethics committee reference number**
28226. IR.IUMS.REC.1395

## Health conditions studied

### 1

**Description of health condition studied**
Acromegaly
**ICD-10 code**
F22.0
**ICD-10 code description**
Acromegaly and pituitary gigantism

## Primary outcomes

### 1

**Description**
IGF-1
**Timepoint**
Before and 3 months after trial onset
**Method of measurement**
Laboratory measurement

### 2

**Description**
Blood pressure
**Timepoint**
0,3 months
**Method of measurement**

Blood pressure monitor

**3**

**Description**
FBS
**Timepoint**
0,3 months
**Method of measurement**
Laboratory

**4**

**Description**
BUN
**Timepoint**
0,3 months
**Method of measurement**
Laboratory

**5**

**Description**
Cr
**Timepoint**
0,3 months
**Method of measurement**
Laboratory

**6**

**Description**
GH
**Timepoint**
0,3 months
**Method of measurement**
Laboratory(RIA)

**7**

**Description**
BMI
**Timepoint**
0,3 months
**Method of measurement**
Calculation

## Secondary outcomes

**1**

**Description**
IGF1
**Timepoint**
Before and 3 months after trial onset
**Method of measurement**
Laboratory measurement-

**2**

**Description**
BMI
**Timepoint**
0,3 months
**Method of measurement**
Calculation

**3**

**Description**
Blood pressure
**Timepoint**
0,3 months
**Method of measurement**
Blood pressure monitor

**4**

**Description**
GH
**Timepoint**
0,3 months
**Method of measurement**
Laboratory measurement-

**5**

**Description**
FBS
**Timepoint**
0,3 months
**Method of measurement**
Laboratory measurement-

**6**

**Description**
BUN
**Timepoint**
0,3 months
**Method of measurement**
Laboratory measurement-

**7**

**Description**
Cr
**Timepoint**
0,3 months
**Method of measurement**
Laboratory measurement-

## Intervention groups

**1**

**Description**
Patients in the first group receive cabergoline 1 mg 3 times weekly for 3 months.
**Category**
Treatment - Drugs

**2**

**Description**
The second intervention group receive raloxifen 60 mg 2

times daily for 3 months.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
The Institute of Endocrinology, Iran University of Medical Sciences

**Full name of responsible person**
Poopak Asadi, MD

**Street address**
Valiasr Ave, Firoozeh street

**City**
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Dr. Seyed Javad Moosavi

**Street address**
Iran University of Medical Sciences, Hemmat highway

**City**
Tehran

**Grant name**

**Grant code / Reference number**

**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**
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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The Institute of Endocrinology, Iran University of Medical Sciences

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## Person responsible for updating data

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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*