# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effect of Cabergoline on rheumatiod Arthritis patient

## Protocol summary

**Summary**

The objective of this study is investigation of cabergoline effects on Rheumatoid arthritis .This study is a cross over clinical trial on Rheumatoid arthritis (ACR 1987 criteria) and activity of RA will be defined as existence of 4 swollen joints and two of these : 6 tender joints, morning stiffness>30 minutes and ESR≥28. Patients should be received DMARDs (diseases modifying slow acting anti rheumatiod drugs)at least for 3-6 months before entry to study .We will not change DMARDs during the intervention but we can joint injection except in third month. Exclusion criteria includes: patient uncompromised, psychological problems, pregnancy and lactation. This study will be done on 10 patients that will divide in 2 groups with 5 patients in every group. Cabergoline (1mgr/week) and placebo (once weekly) will be given to patients by another colleague for 3 months. We record activity criteria and after one month as wash out period, we will change drug to another (cabergoline or placebo). After second 3 months we will record activity criteria again. ESR and prolactin will be measured on 0,3,4,7 months. We will analysis result as change in disease activity (morning stiffness, swollen and tender joints, visual analogue score and ESR, prolactin)

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138802061828N2**
Registration date: **2009-06-29, 1388/04/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2009-06-29, 1388/04/08

**Registrant information**

**Name**

Maryam Mobini

**Name of organization / entity**

Mazandaran University of Medical Sciences and Health Services

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Mazandaran University of Medical Sciences and Health Services

**Expected recruitment start date**

2009-05-22, 1388/03/01

**Expected recruitment end date**

2010-04-21, 1389/02/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Cabergoline on rheumatiod Arthritis patient

**Public title**

Effect of Cabergoline on rheumatiod Arthritis patient

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: patient with Rheumatoid Arthritis (RA) based on ACR (american college of romahthology) 1987 criteria and activity of RA will be defined as existence of 4 swollen joints and two of these : 6 tender joints, morning stiffness>30 minutes and ESR≥28. Patients should be received DMARDs (diseases modifying slow acting anti rheumatiod drugs) at least for 3-6 months

before entry to study. Exclusion criteria includes: patient uncompromised, psychological problems, pregnancy and lactation.

**Age**
No age limit

**Gender**
Both

**Phase**
2

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **10**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Mazandaran University of Medical Sciences and Health Services

**Street address**
Imam Sq, Joybar 3way, Start of valiye asr highway

**City**
Sari

**Postal code**

**Approval date**
empty

**Ethics committee reference number**
88-18

## Health conditions studied

### 1

**Description of health condition studied**
Rheumatoid arthritis

**ICD-10 code**
M05.8

**ICD-10 code description**
Other seropositive rheumatoid arthritis

## Primary outcomes

### 1

**Description**
the number of tender joints

**Timepoint**
before prevention and 3,4 and 7 month after prevention

**Method of measurement**
taking history and Questionnaire

### 2

**Description**
morning stiffness

**Timepoint**
before prevention and 3,4 and 7 month after prevention

**Method of measurement**
taking history and Questionnaire

### 3

**Description**
the number of swollen joints

**Timepoint**
before prevention and 3,4 and 7 month after prevention

**Method of measurement**
examination

### 4

**Description**
pain

**Timepoint**
before prevention and 3,4 and 7 month after prevention

**Method of measurement**
VAS

## Secondary outcomes

### 1

**Description**
ESR

**Timepoint**
before intervention and 3,4 and 7 mounth after treatment

**Method of measurement**
labratory

### 2

**Description**
prolactine

**Timepoint**
before intervention and 3,4 and 7 mounth after treatment

**Method of measurement**
labratory

## Intervention groups

### 1

**Description**

First group: Cabergoline (1mgr/week) for 3 months and after one month as wash out period, we will change drug to placebo

**Category**

Treatment - Drugs

**2**

**Description**

Second group: Placebo (once weekly) for 3 months and after one month as wash out period, we will change placebo to cabergoline (1mgr/week)

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Tuba clinic

**Full name of responsible person**

Marayam Mobini

**Street address**

Khazar Blv

**City**

Sari

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences and Health Services

**Full name of responsible person**

Sayed Jalal Hosseini mehr

**Street address**

Moalem sq.

**City**

Sari

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mazandaran University of Medical Sciences and Health Services

**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**

Mazandaran Univercity of medical sciences and Health ervices

**Full name of responsible person**

Motahareh Kheradmand

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## Person responsible for scientific inquiries

**Contact**

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Mazandaranl Univercity of medical sciences and Health services

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**Position**

Rheumatologist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

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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*