

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Cabergoline on rheumatoid 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 $\geq$ 28. Patients should be received DMARDs (diseases modifying slow acting anti rheumatoid 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

+98 15 1324 4142

Email address

mmobini@mazums.ac.ir

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 rheumatoid Arthritis patient

Public title

Effect of Cabergoline on rheumatoid Arthritis patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with Rheumatoid Arthritis (RA) based on ACR (american college of romahtology) 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 $\geq$ 28. Patients should be received DMARDs (diseases modifying slow acting anti rheumatoid 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 month after treatment

Method of measurement

labratory

2

Description

prolactine

Timepoint

before intervention and 3,4 and 7 month 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 University of medical sciences and Health services

Full name of responsible person

Motahareh Kheradmand

Position

Master of science in nursing

Other areas of specialty/work

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Moallem square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of medical sciences and Health services

Full name of responsible person

Maryam Mobini

Position

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Full name of responsible person

Elahe Adibi

Position

Medicine student

Other areas of specialty/work

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Razi street-imam khomani hospital

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elahe.adibi@yahoo.com

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