

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Bromocriptin effect on disease activity index in rheumatoid arthritis

Protocol summary

Summary

The goal of this study is evaluation of oral bromocriptin effect on rheumatoid arthritis disease activity ((DAS28 score). Population study will be rheumatoid arthritis patients referred to the Rheumatology Clinic of Al-zahra Hospital. Sample size in this study is 80. This study is a randomized double blind controlled trial that will start at the spring 2010 and will continue to spring 2011. The primary endpoint is improvement of clinical symptoms and laboratory parameters of patients following oral consumption of bromocriptin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008121778N3**
Registration date: **2010-08-12, 1389/05/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-08-12, 1389/05/21

Registrant information

Name

Mansour Salesi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1265 1983

Email address

salesi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2010-04-30, 1389/02/10

Expected recruitment end date

2011-04-30, 1390/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Bromocriptin effect on disease activity index in rheumatoid arthritis

Public title

Bromocriptin and rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Rheumatoid arthritis patients (proved by ACR criteria) that greater than 16 years old with active R.A (DAS>4) despite conventional thrapy.

Exclusion criteria: Drug reaction, lapse from the study, Immigration or death, contraindications for bromocriptin

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Hezar Jarib Boulevard

City

Isfahan

Postal code

8158697851

Approval date

2010-01-10, 1388/10/20

Ethics committee reference number

103425 /4/12/پ

Health conditions studied**1****Description of health condition studied**

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Seropositive rheumatoid arthritis

Primary outcomes**1****Description**

Clinical and laboratory findings

Timepoint

Before the study and 3 months later

Method of measurement

DAS28, ESR, VAS, Prolactin

Secondary outcomes

empty

Intervention groups**1****Description**

two placebo tablet per day for 3 months

Category

Placebo

2**Description**

Bromocriptin oral pills 2.5 mg two tablet per day for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Mansour Salesi

Street address

Sofe Avenue

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor of research, Isfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research

Street address

Vice chancellery of research, Isfahan University of Medical Sciences

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor of research, Isfahan 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

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mansour Salesi

Position

Rheumatologist/Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Somayeh Sadeghi

Position

Resident of Internal Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mansour Salesi

Position

Rheumatologist/Assistant professor

Other areas of specialty/work

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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