

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Effect of vitamin K1 supplementation on some biochemical markers and clinical status in women with rheumatoid arthritis

Protocol summary

Summary

The aim of this study is to evaluate the effect of vitamin K1 supplementation on some biochemical markers and clinical status in women with rheumatoid arthritis. 64 women with RA who are 20-50 years old and meet the inclusion criteria would be recruited from clinics of Tabriz University of medical sciences. The patients are assigned as a double blind manner into placebo or intervention groups based on age and severity of disease. The intervention group receives oral vitamin K1 supplement one tablet for 60 days (10 mg vitamin K1/tablet) and the placebo group receive placebo in the same way. Serum hsCRP, IL-6, TNFa, MMP-3, RF, TC, TG, HDL are measured at baseline and after intervention in 2 groups. Also, BMI, waist and hip circumference, dietary habits, physical activity and anxiety state are evaluated.

General information

Acronym

RA

IRCT registration information

IRCT registration number: **IRCT201205203140N4**

Registration date: **2012-07-29, 1391/05/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-29, 1391/05/08

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Student Research Committee, Vice Chancellor for Research, Nutrition and Health Faculty, Tabriz University of Medical Sciences

Expected recruitment start date

2012-07-20, 1391/04/30

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin K1 supplementation on some biochemical markers and clinical status in women with rheumatoid arthritis

Public title

Effect of vitamin K1 supplementation in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female rheumatoid arthritis patients who have ACR criteria 1987 for RA, age 20-50 years old; not changing the treatment protocol since 2 months prior to the study; mild to moderate disease severity.
Exclusion criteria: pregnancy; lactation; postmenopausal state; receiving hormone replacement therapy; smoking or exposure to passive smoking; receiving antioxidant or

anti-inflammatory supplements since 1 month prior to the study; Presence of cancer, diabetes mellitus, hormonal dysfunctions, undernutrition, severe obesity (BMI>40), uncontrolled hypertension, renal and hepatic diseases, digestion disorders, changing treatment and lifestyle, PT abnormality.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

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

Ethics committee of Tabriz university of medical sciences

Street address

Research Vice-chancellor, central building, number 2, Tabriz university of medical sciences, Golgasht street

City

Tabriz

Postal code

Approval date

2012-05-08, 1391/02/19

Ethics committee reference number

5/4/1683

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Clinical Outcomes

Timepoint

before and after intervention (60 days)

Method of measurement

by means of DAS-28 validated questionnaire

2

Description

serum levels of IL-6, hsCRP, TNFa

Timepoint

before and after intervention (60 days)

Method of measurement

by means of special kits in Tabriz Pharmaceutical Research Center

3

Description

serum level of RF (Rheumatoid Factor)

Timepoint

before and after intervention (60 days)

Method of measurement

by means of special kit in Tabriz Pharmaceutical Research Center

4

Description

Lipid profile (TC,TG,HDL,LDL)

Timepoint

before and after intervention (60 days)

Method of measurement

all parameters as HDL-C- Total cholesterol- triglyceride with enzymatic kits except LDL-c (by means of Friedwald formula)

5

Description

Serum level of matrix metalloproteinases-3 (MMP-3)

Timepoint

before and after intervention (60 days)

Method of measurement

by means of special kit in Tabriz Pharmaceutical Research Center

Secondary outcomes

1

Description

Dietary Intake of Energy, Nutrients and Comparison with RDA

Timepoint

before and after intervention (60 days)

Method of measurement

dietary record for 3 days

2

Description

anthropometric indicator (BMI)

Timepoint

before and after intervention (60 days)

Method of measurement

Body weight without shoes with calibrated scale,
Standing height without shoes are measured. BMI was
calculated with this equation: $W(kg) / H(m)^2$

Intervention groups

1

Description

intervention group: 10 mg vitamin K1 every day for 60
days - after a meal - chewable tablet

Category

Treatment - Drugs

2

Description

control group: placebo every day for 60 days- chewable
tablet -after a meal

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golgasht clinic

Full name of responsible person

Dr. Susan Kolahi

Street address

Azadi avenue, close to Golgasht avenue, Golgasht
clinic-Third Floor

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Nutrition and Health
Faculty in Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi, Dr Ostadrahimi

Street address

Health and nutrition school, Attar Neishabouri
Avenue, Golgasht street

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Nutrition and Health
Faculty in Tabriz 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

Health and Nutrition Faculty, Tabriz University of
medical sciences

Full name of responsible person

Dr. Bahram Pourghassem Gargari

Position

PHD of nutritional biochemistry, Associate Professor
of Nutrition and Health Faculty

Other areas of specialty/work

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Health and Nutrition Faculty, Tabriz university of
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Full name of responsible person

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Position

MS student of nutrition

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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