

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of soy- corn bread on malnutrition indices, oxidative stress, and quality of life in celiac patients

Protocol summary

Summary

To investigate the effect of soy- corn bread on oxidative stress, malnutrition indices and quality of life in patients with Celiac Disease(CD) the present study has been designed. This study includes two phases: soy- corn bread production (phase I) and a single blind clinical trial (Phase II).The population study are patients with celiac disease (less than 18 years) who dont suffer from other chronic diseases. Patients assigned randomly into two groups: soy- corn bread (intervention) and corn bread (control). Before and after the intervention , weight,, BMI, MAC, MAMC and TSF, albumin , MDA, transglutaminase and endomysial antibodies will be measured and quality of life questionnaire for children with CD (CDDUX) will be completed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050217522N1**

Registration date: **2014-05-20, 1393/02/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-20, 1393/02/30

Registrant information

Name

Maryam Taghdir

Name of organization / entity

Baqiyatallah University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 5511

Email address

mtaghdir@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of soy- corn bread on malnutrition indices, oxidative stress, and quality of life in celiac patients

Public title

The effect of soy- corn bread on malnutrition indices in celiac patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: less than 18 years old ,confirmed celiac disease, not to have chronic disease((renal , liver and lung diseases),reside in Shiraz, exclusion criteria:diagnosis of chronic diseases during the study.

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for research affairs

Street address

Shiraz university of medical sciences-Zand St- Shiraz

City

Shiraz

Postal code

1978-71345

Approval date

2014-04-26, 1393/02/06

Ethics committee reference number

CT-9360-6980

Health conditions studied

1

Description of health condition studied

Celiac disease

ICD-10 code

K90.0

ICD-10 code description

Coeliac disease

Primary outcomes

1

Description

albumin

Timepoint

twice, at the beginning and the end of the study

Method of measurement

autoanalyzer

2

Description

BMI

Timepoint

twice, at the beginning and the end of the study,

Method of measurement

$Wt(kg)/Ht(m^2)$

3

Description

MAC

Timepoint

twice, at the beginning and the end of the study

Method of measurement

nonstretchable tape

4

Description

MAMC

Timepoint

twice, at the beginning and the end of the study

Method of measurement

$MAMC (mm) = MAC (mm) - (\pi \cdot TSF (mm))$

5

Description

TSF

Timepoint

twice, at the beginning and the end of the study

Method of measurement

By caliper

Secondary outcomes

1

Description

MDA

Timepoint

twice, at the beginning and the end of the study

Method of measurement

spectrophotometer

2

Description

transglutaminase antibody

Timepoint

twice, at the beginning and the end of the study

Method of measurement

ELISA

3

Description

endomysial antibody

Timepoint

twice, at the beginning and the end of the study

Method of measurement

ELISA

4

Description

food intake

Timepoint

twice, at the beginning and the end of the study

Method of measurement

food recall

5

Description

quality of life

Timepoint

twice, at the beginning and the end of the study

Method of measurement

QOL questionnaire for celiac disease

Intervention groups

1

Description

intervention group: soy- corn bread for 3 months

Category

Treatment - Other

2

Description

control group: corn bread, for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Namazi hospital

Full name of responsible person**Street address****City**

Shiraz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Moosa Salehi

Street address

School of nutrition and food sciences, Shiraz
University of Medical Sciences

City

Shiraz

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

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Taghdir

Position

PhD student

Other areas of specialty/work**Street address**

School of nutrition and food sciences, Shiraz University
of Medical Sciences

City

Shiraz

Postal code**Phone**

+98 71 1725 7288

Fax**Email**

mtaghdir@gmail.com, marta602@yahoo.com, taghdir
m@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Moosa Salehi

Position

Associate professor in nutrition

Other areas of specialty/work**Street address**

School of nutrition and food sciences, Shiraz
University of Medical Sciences

City

Shiraz

Postal code**Phone**

+98 71 1725 7288

Fax**Email**

moosasalehi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Taghdir

Position

PhD student

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code

Phone

+98 71 1725 7288

Fax

Email

mtaghdir@gmail.com,marta602@yahoo.com,taghdir

m@sums.ac.ir

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