Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 21 8755 5511

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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(m2)

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) – (π . 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 and 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
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Person responsible for scientific inquiries

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Dr. Moosa Salehi
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Associate professor in 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