

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of gluten free food diet in treatment of steroid resistant nephrotic syndrome patients

Protocol summary

Study aim

Efficacy of gluten free food diet in decreasing proteinuria in steroid resistant nephrotic syndrome patients

Design

clinical trial without control group, single group, designed of 25 patients, non randomised

Settings and conduct

25 patients of steroid resistant nephrotic syndrome in tabriz emam reza hospital that has given 1-2 mg/kg of prednisolon for at least 2 month and his/her proteinuria has not decreases at least for 50% will be given gluten free diet for 2 month. patients will be studied for renal functions, urea, cr, serum albumin, urine analysis, 24 hour urine protein, routine lab and lipid profile before and after diet

Participants/Inclusion and exclusion criteria

inclusion criteria 1)steroid resistant nephrotic syndrome patients 2)patients that incline to participate exclusion criteria 1) pregnant patients 2) diabetic nephropathy patients

Intervention groups

steroid resistant nephrotic syndrome patients before and after using gluten free diet , control group patients in this study are patient before using gluten free diet. we select the patients who were on steroid and impressiveness resistant for at least 6 months and resistant to treatment. then these patients to place on gluten free diet for 2 months. the diet is supply by Isuda diet company

Main outcome variables

decreasing proteinuria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200512047415N1**

Registration date: **2021-05-30, 1400/03/09**

Registration timing: **retrospective**

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

Registration date

2021-05-30, 1400/03/09

Registrant information

Name

Hamid Tayyebi Khosroshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3177 1042

Email address

tayebikhosroshahi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2021-01-18, 1399/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of gluten free food diet in treatment of steroid resistant nephrotic syndrome patients

Public title

Efficacy of gluten free food diet

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

steroid resistant nephrotic syndrome patients patients that incline to participate

Exclusion criteria:

pregnant patients diabetic nephropathy patients

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Faculty of medicine, next to Imam Reza General Hospital , Across from Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2020-06-29, 1399/04/09

Ethics committee reference number

IR.TBZMED.REC.1399.324

Health conditions studied

1

Description of health condition studied

steroid resistant nephrotic syndrome patients

ICD-10 code

N04

ICD-10 code description

Primary outcomes

1

Description

decreasing in proteinuria before and after 2 month of gluten free diet

Timepoint

before and after 2 month of gluten free diet

Method of measurement

comparing amount of proteinuria before and after 2 month of gluten free diet

Secondary outcomes

empty

Intervention groups

1

Description

25 patients of steroid resistant nephrotic syndrome in tabriz emam reza hospital that has given 1-2 mg/kg of prednisolon for at least 2 month and his/her proteinuria has nor decreases at least for 50% will be given gluten free diet for 2 month. patients will be studied for renal functions, urea, cr, serum albumin, urine analysis, 24 hour urine protein, routine lab and lipid profile before and after diet. The control group are the patients before getting gluten free diet.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz emam reza hospital

Full name of responsible person

heidar hazemi

Street address

Tabriz emam reza hospital, golgasht st, azadi ave

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tayebikhosroshahi@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamid Tayebi khosroshahi

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Imam Reza General Hospital , Across from Central
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Heidar Hazemi

Position

resident of internal medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Demographic information and raw data obtained from experiments All data are accessible

When the data will become available and for how long

immediately after publishing results

To whom data/document is available

everybody in related fields of study

Under which criteria data/document could be used

everybody in related fields of study with noting the source of data

From where data/document is obtainable

contact this email adress : dr.hazemi59010@gmail.com

What processes are involved for a request to access data/document

If the mentioned access conditions are met, the data will be delivered within 2 weeks after contacting the mentioned email

Comments