

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of the occurrence, effect and side effects of Cyclophosphamide and rituximab in the treatment of children with NEPHROTIC SYNDROME resistance to STEROID that referred to Hazrate Massumeh hospital .

Protocol summary

Study aim

Evaluation of the occurrence, effect and side effects of Cyclophosphamide and rituximab in the treatment of children with NEPHROTIC SYNDROME resistance to STEROID

Design

102 patients with Steroid-Resistant Nephrotic Syndrome were randomly divided into two groups and each group received a drug, and in parallel, each group was examined.

Settings and conduct

Qom hazrat Masoomeh hospital

Participants/Inclusion and exclusion criteria

All patients with NEPHROTIC SYNDROME resistance to STEROID

Intervention groups

Patients with steroid resistant nephrotic syndrome were divided into two groups. The first group received cyclophosphamide and the second group received rituximab.

Main outcome variables

Frequent relapses; Steroid dose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170527034146N2**

Registration date: **2019-02-18, 1397/11/29**

Registration timing: **retrospective**

Last update: **2019-02-18, 1397/11/29**

Update count: **0**

Registration date

2019-02-18, 1397/11/29

Registrant information

Name

mohsen akhavansepahi

Name of organization / entity

Hazrat massomeh hospital

Country

Iran (Islamic Republic of)

Phone

+98 25 3665 1802

Email address

makhavan@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-09-23, 1397/07/01

Trial completion date

2018-09-23, 1397/07/01

Scientific title

Evaluation of the occurrence, effect and side effects of Cyclophosphamide and rituximab in the treatment of children with NEPHROTIC SYNDROME resistance to STEROID that referred to Hazrate Massumeh hospital .

Public title

Evaluation of the occurrence, effect and side effects of Cyclophosphamide and rituximab in the treatment of children with NEPHROTIC SYNDROME resistance to STEROID that referred to Hazrate Massumeh hospital .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patient whit nephrotic syndrome resistance to steroid
whit age 1-18 yr

Exclusion criteria:

All patient who do not have steroid-resistant Nephrotic
Syndrome for example patient with steroids depended
syndrome. All patient who did not accept treatment All
patient who died All patient who did not follow up

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **102**

Actual sample size reached: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple random sampling method was used for the
selected sample and was divided into two groups of
intervention and control by simple randomized
distribution method. The randomized random number
tool is the unit of individual cadastre. The patients were
divided into two equal groups, regardless of sex and age,
and on the basis of resistant to steroid therapy. The
intervention group, in addition to prednisolone, received
Ritoximab, which received a cyclophosphamide drug
control group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of QOM University of Medical
Sciences

Street address

EMAM STREET.

City

QOM

Province

Ghoum

Postal code

3719815532

Approval date

2017-09-05, 1396/06/14

Ethics committee reference number

IR.MUQ.REC.1396.77

Health conditions studied

1

Description of health condition studied

Nephrotic syndrome resistance to steroide

ICD-10 code

N04.8

ICD-10 code description

Nephrotic syndrome with other morphologic changes

Primary outcomes

1

Description

The frequency of relapse of the disease before and after
taking the cyclofosfamide and ritoximab

Timepoint

Weekly

Method of measurement

Urin analysis of proteine

2

Description

Dosage of the prednisolon before and after taking the
medication

Timepoint

weekly

Method of measurement

check liste

Secondary outcomes

1

Description

Number of relapses after receiving rutioxime and
cyclophosphamide.

Timepoint

weekly

Method of measurement

Urinalysis. Patient's disease

2

Description

Dosage of Steroids after receiving medication

Timepoint

weekly

Method of measurement

check liste

Intervention groups

1

Description

Intervention group: Intervention group: In addition to prednisolone, ritoximab with 375 mg / m² / day was given intravenously and weekly for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Control group: In addition to prednisolone, cyclophosphamide dose of 2 mg per kg per day For three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

hazrat masoomeh hospital

Full name of responsible person

mohsen akhavan sepahi

Street address

Emam street

City

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Province

Ghous

Postal code

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Phone

+98 25 3665 1801

Email

makhavan@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Hosein Saghafi

Street address

Ghadir Street

City

Qom

Province

Ghous

Postal code

3719815532

Phone

+98 25 3665 1804

Fax

Email

Register@muq.ac.ir

Web page address

<https://fa.irct.ir/user/trial/37066/update/sponsor>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghous 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

2

Sponsor

Name of organization / entity

Assistant research in Qom medical university

Full name of responsible person

Hosein Saghafi

Street address

Ghadir Street

City

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Province

Ghous

Postal code

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Phone

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Email

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Web page address

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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

Assistant research in Qom medical university

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

Ghoush University of Medical Sciences

Full name of responsible person

Mohsen Akhavan Sepahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

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Web page address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoush University of Medical Sciences

Full name of responsible person

Mohsen Akhavan Sepahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Web page address

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Person responsible for updating data

Contact

Name of organization / entity

Ghoush University of Medical Sciences

Full name of responsible person

Mohsen Akhavan Sepahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Web page address

https://fa.irct.ir/user/trial/37066/update/data_updater_contact

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the details, such as information about the original message or its cover, can be shared.

When the data will become available and for how long

Since 1399

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Clinical analyses and clinical findings

From where data/document is obtainable

Principal Mohsen Akhavan Sepahi. E-mail: makhavan@muq.ac.ir

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

Apply by e-mail to Mohsen Akhavan Sepahi

Comments