Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

The role of insulin therapy in reducing critical illness polyneuropathy and myopathy in pediatric intensive care unit

Protocol summary

Summary

Objectives: In this study the effect of insulin as an effective treatment in reducing critical illness of polyneuropathy and myopathy during one year and a half in 30 cases of patients who undergo mechanical ventilation in pediatric intensive care unit of Tabriz Children's Hospital will be studied. Design: The study is clinical trial and 30 mentioned patients are divided into two groups; In first group with 15 patient insulin is used in order to keep blood sugar in range of 140-180 milligram per decilitre.In second group with 15 patient,distilled water as placebo will be used. Setting and conduct: Appropriate protocol will be continuous injection of insulin as drip.Injection of distilled water will be also continuous and as drip like insulin.Note that the injection will be as same as first group and will be done by a person with no information about polymyopathy and neuropathy. Participants including major eligibility criteria: In this study the effect of insulin as an effective treatment in reducing critical illness of polyneuropathy and myopathy during one year and a half in 30 cases of patients who undergo mechanical ventilation in pediatric intensive care unit of Tabriz Children's Hospital will be studied.Confounding variables are important in this study and the following people are excluded from study; spinal cord injuries; patients with Guillain Barre Syndrome; myasthenia gravis; patients with central nervous system problems or neuromuscular disease causing muscle weakness and paralysis before or during the hospitalization; hypophosphatemia. Interventions: In first group with 15 patients if blood sugar rises more than 180 milligram per decilitre insulin will be injected 0.5 unit per kilogram with serial control of blood sugar each hour (of course blood sugar will be kept between 140 to 180 milligram per decilitre until patient is connected to mechanical ventilator).In second control group with 15 patients distilled water as placebo will be used.The form of administring will be 0.5 unit per kilogram with serial control of blood sugar each hour like first group. Main outcome measures variables: Our main outcome measures variable is blood sugar.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108117295N1**
Registration date: **2012-02-16, 1390/11/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-02-16, 1390/11/27

Registrant information

Name
Nemat Bilan
Name of organization / entity
Tabriz Univercity of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1526 2280
Email address
bilan@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

The financial resources of the Research will be provided by Institute of Tuberculosis and Lung Disease, TABRIZ University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of insulin therapy in reducing critical illness polyneuropathy and myopathy in pediatric intensive care unit

Public title

The role of insulin therapy in reducing critical illness polyneuropathy and myopathy in pediatric intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria and who are under investigation in this study are the following: In this study,during one year and a half,30 of patients admitted to the pediatric intensive care unit of Tabriz Children's Hospital and are more than one week under mechanical ventilation and in the course of their hospitalization experience hyperglycemia (more than 180 milligram per decilitre) are divided into two groups; In first group with 15 patient insulin is used in order to keep blood sugar in range of 140-180 milligram per decilitre (until the patient is connected to the ventilator); In second group with 15 patient,distilled water as placebo will be used (Note that injection will be done by a person who has no information about the polyneuropathy and myopathy). Confounding variables are important in this study and the following people are excluded from study; spinal cord injuries; patients with Guillain Barre Syndrome; myasthenia gravis; patients with central nervous system problems or neuromuscular disease causing muscle weakness and paralysis before or during the hospitalization; hypophosphatemia. Appropriate methods to control confounding variables are according to observation,periods of physical examination,laboratory results such as blood and cerebro spinal fluid tests and EMG and NCV. It should be noted that the removal of these patients are so that in each point of the study (before the start of or during the study) if each of 5 problems above found by methods such as Electromygraphy and testing of cerebrospinal fluid or physical examination period,the patient will be excluded.

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

The ethics committee of Tabriz University of Medical Sciences, Faculty of Medicine

Street address

Faculty of Medicine, Tabriz University of Medical Sciences, Golgasht Avenue, Tabriz

City

Tabriz

Postal code

5165665931

Approval date

2011-06-06, 1390/03/16

Ethics committee reference number

2109.4.5

Health conditions studied

1

Description of health condition studied

polyneuropathy and myopathy

ICD-10 code

E10,E11.E1

ICD-10 code description

Diabetic polyneuropathy

Primary outcomes

1

Description

blood glucose

Timepoint

Serial monitoring of blood glucose per hour (the aim of maintaining blood glucose range 140-180 milligram per decilitre)

Method of measurement

Glucometry

Secondary outcomes

1

Description

Polyneuropathy and myopathy

Timepoint

After extubation

Method of measurement

Electromyography

Intervention groups

1

Description

In this study,during one year and a half,30 of patients admitted to the pediatric intensive care unit of Tabriz Children's Hospital and are more than one week under mechanical ventilation and in the course of their hospitalization experience hyperglycemia (more than 180 milligram per decilitre) are divided into two groups; In first group with 15 patients,in which the intervention is done, insulin is used in order to keep blood sugar in range of 140-180 milligram per decilitre (until the patient is connected to the ventilator).Appropriate protocol will be continuous injection of 0.5 unit per kilogram insulin as drip with serial control of blood sugar each hour with the goal of keeping blood sugar between 140-180 milligram per decilitre. Note that the injection will be as same as first group and will be done by a person with no information about polymyopathy and neuropathy.

Category

Treatment - Drugs

2

Description

In second group with 15 patients which is called control group,distilled water as placebo will be used.Appropriate protocol in using distilled water,like insulin injection in intervened group,is continuous injection of 0.5 unit per kilogram insulin as drip with serial control of blood sugar each hour.Note that the injection will be done by a person with no information about polyneuropathy and myopathy and the injected substance.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Hospital of Tabriz

Full name of responsible person

Nemat Bilan

Street address

Children's Hospital, Sheshgalan Avenue, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Tuberculosis Research Centre, Vice chancellor for research, Faculty of Medicine, Tabriz University of Medical Sciences, Golgasht, Tabriz

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, 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

Tabriz University of Medical Sciences

Full name of responsible person

Shahram Sadegvand

Position

Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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