

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

effectiveness study of nandrolone on facilitate weaning in prolonged weaning patients

Protocol summary

Study aim

Determine the effectiveness of nandrolone injection in facilitating the separation of patients under long-term mechanical ventilation

Design

A simple random sampling (Slip the Coin) with a sample size of 30 (control and control), will be in the third phase of the trial.

Settings and conduct

In the ICU of Mousavi Hospital in the area of people with long mechanical ventilation and inclusion criteria, a simple random sampling method (Slip the Coin) was applied blindly to the researcher and performer of the project (assistant investigator) in patients with the same Apache screw in Two intervention and control groups will be conducted.

Participants/Inclusion and exclusion criteria

People between the ages of 20 and 70 and those of the same sex with the same apache sclerosis are enrolled in the entry criteria, and those who have, in any case, become unstable and require additional interventions.

Intervention groups

In this study, patients who have been infected within 3 days to 3 weeks since they were inoculated or who have not been able to extol. In the range of 20 to 70 years, men and women with the same Apache scroun are randomly divided into intervention and control groups. Each of the two groups will be at least 15 people, with a total of 30 people. For patients in the intervention group, 1 vial 25 mg of anabolic nandrolone was injected intramuscularly 2 times a day to 1 week (14 doses), and then daily weaning was evaluated, and changes in the conditions of the subjects using the checklist for the preparation of Bern's separation in both groups Control and control are measured.

Main outcome variables

Age Sex Device dependency time Intervention factor
Duration of admission to ICU Cause of hospitalization The reason for this

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040695N1**

Registration date: **2018-10-27, 1397/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-27, 1397/08/05**

Update count: **0**

Registration date

2018-10-27, 1397/08/05

Registrant information

Name

Mohammadreza Zeraati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0000

Email address

mohammadrezazeraati@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effectiveness study of nandrolone on facilitate weaning in prolonged weaning patients

Public title

Study of the effect of Nandrolone ampoule in facilitating the separation of mechanical ventilation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with long-term separation of mechanical ventilation (over SBT 3 or 7 days from the first SBT to 3 weeks) separate inspiration weakness (caused by myopathy or neuropathy caused by respiratory muscles for any reason). Age 20 to 70 years Sepsis or febrile illness that causes a kind of neuropathy. Lack of lung disease (such as nano-pulmonary pleural effusion-respiratory failure-pulmonary mass and COPD) Patients with the same nutrition or gavage Length of stay in ICU less than 21 days. No electrolyte imbalance NIF having > 30-

Exclusion criteria:

Reintubation Patient death before ICU clearance NPO becoming patient during examination Incidence of pulmonary edema, ARDS, pleural effusion and ventilator pneumonia Electrolyte disturbances (hypokalemia, etc.) at any time during the study. Dissatisfaction with the patient's companions Contraindication for the injection of nandrolone such as CHF, recent history of IHD or MI, obstructive europoplasty (BPH) in men, hematocrit over 50 (erythrocytosis), and chronic kidney and liver disease (Increase LFT)

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and assistant researcher do not know which medicine was injected.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences , Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.ZUMS.REC.1397.63

Health conditions studied

1

Description of health condition studied

All patients have long-term ventilation with the same Apache screw

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Facilitate separation of ventilators in patients with long-term mechanical ventilation

Timepoint

In 3 stages, 3, 5 and 7 per week, variables such as static capacity, R.S.R.I, I.W.I, CORP Index

Method of measurement

Questionnaire (Static Compliace, R.S.R.I, I.W.I, CORP Index)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: تزریق دارو نما Nandrolone intramuscular injection twice a day for one week

Category

Placebo

2

Description

Control group: Injection drug
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi Hospital ICU Ward

Full name of responsible person

Mohammad Reza Zeraati

Street address

No. 4513956183, Mousavi Hospital, Gavazang Ave.,
Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

Mousavihospital@zums.ac.ir

Web page address

http://zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohammad Reza Zeraati

Street address

No. 4513956183, Mousavi Hospital, Gavazang Ave.,
Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

Mousavihospital@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mohammad Reza Zeraati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

No. 4513956183, Mousavi Hospital, Gavazang Ave.,
Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

mohammadrezazeraati@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mohammad Reza Zeraati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

No. 4513956183, Mousavi Hospital, Gavazang Ave.,
Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

mohammadrezazeraati@zums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Mohammad Reza Zeraati

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

No. 4513956183, Mousavi Hospital, Gavazang Ave.,
Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Email

mohammadrezazeraati@zums.ac.ir

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

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Data analysis will be done using the spss v 19 software.
The data will be used after the data collection in the
software to describe the quantitative variables of the
mean and standard deviation and describing the
qualitative variables of the frequency. In analyzing
variables, for comparison of quantitative variables,
following the normal T-test, otherwise, man-Witney U is
used and the chi2 qualitative variables will be used.

When the data will become available and for how long

18 months

To whom data/document is available

Dr. Somayeh Abdollahi Sabet

Under which criteria data/document could be used

To analyze

From where data/document is obtainable

Dr. Somayeh Abdollahi Sabet-Medical Assistant Professor
-09124195270

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

One year

Comments