

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the outcomes of Weaning with current methods and IWI-based in patients admitted to ICU of selected hospitals in Tehran During 2011-2012

Protocol summary

Summary

First Step: A Control Group Of Patients In The ICU, 62 Patients Undergoing Mechanical Ventilation Are More Than 24 Hours As Controls Are Evaluated. Inclusion Criteria Included Age 80-18 Years, Absence Of Neurological And Neuropsychiatric Diseases - Muscular, Use The Minimum Dose Of Sedative Drugs (Light Relaxation Time Scale As Palma And Cooke 18-15) And No Addiction Opium. Information Required By The Tables And The Questionnaire Attached Proposal, Will Be Collected From The Records Of Patients Hospitalized In The ICU. At This Stage, the Researcher Is Present Only As Observers. The Primary Criterion's For The Separation Of Eight Patients In This Group Are: 1 - The Start of Mechanical Ventilation On The Sides Or Dropped. 2-CT <38.5 0 3 - Hb $\geq$ 8 gr / DI 4 Pao2 $\geq$ 60 mmhg - 5 - Sao2 $\geq$? With Fio2 $\leq$ 40% 6 - PEEP $\leq$ 8 Cmh2o 7 - F / TV $\leq$ 105 8 - Use the Minimum Dose Of Drugs Sedative Before Separation, All Patients with PSV = 8-10 Cmh2o, PEEP = 5cmh2o, Fio2 <40% Were Ventilated According To The Physician, Patients Are Removed From The Device Under The SBT With A T-Piece With Are The Average Of 2 Hours. During The First Minutes before Separation with The ABG And Calculation, Cst, Rs, MV, Pao2 / Fio2 F / TV And ... Standard Index Of Separation: $IWI = (Cst, Rs * Sao2) / (F / TV)$ Is Calculated. If There Are Favorable Conditions With Your Doctor, Extubation Is Performed. After Extubation, 48 Hours control Clinical Status Is Considered. Back To The Mechanical Ventilation For Patients With Medical Conditions That Are Completely Unaware Of The Study And The Index Is To Be Taken. Second Stage: The Eight Criteria IWI Index Separation And Isolation Of Patients To Physicians And Nurses In Charge Of The Mechanical Ventilator, Is Taught. The Other 62 Patients According To Inclusion Criteria Are Enrolled. Contextual Information from The Records Of The Mining Sector And Will Be Recorded. 8 The Primary

Criterion For The Separation To Be Evaluated In Patients On A Daily Basis. All Patients Before Separation, With Fio2 <40% PEEP = 5cmh2o, PSV = 8-10 Cmh2o, And They Were Ventilated During The First Minutes Before Separation With The ABG And Calculate F / TV, Cst, MV, Pao2 / Fio2. The IWI Index Is Calculated By The Medical Team In Case Of IWI $\geq$ 25 Conditions, With The Doctor, Patients With T-Piece SBT With An Average Period Of 2 Hours To Start. If There Is An Effective Cough (Subjective Evaluation By The Research Team) And The Stability Condition (Assessed Objectively By The Glasgow Scale 4 Score And GCS), Is The Readiness For Extubation. After Extubation, The Patient Is Evaluated For 48 Hours. Third Stage: The Rate of Successful and Unsuccessful Isolation of the Mechanical Ventilator in the Two Groups Are Compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203282996N9**

Registration date: **2012-04-05, 1391/01/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-05, 1391/01/17

Registrant information

Name

Seyyed Davood Tadrissi

Name of organization / entity

Baghiatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2228 9941

Email address
sdt1343@bmsu.ac.ir

Recruitment status
Recruitment complete

Funding source
Baqyatallah University of Medical Sinence

Expected recruitment start date
2011-12-22, 1390/10/01

Expected recruitment end date
2012-12-21, 1391/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the outcomes of Weaning with current methods and IWI-based in patients admitted to ICU of selected hospitals in Tehran During 2011-2012

Public title
Comparison the outcomes of Weaning with current methods and IW

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria : - Patient >18 Years Up To 80 Years Old - ventilator time >24hr - Non neurological And Intramuscular Disease - None Or A Minimal Dose Of Sedative Drugs -Non Addiction , Heavy Smokers - Not Admitted In ICU-open heart Exclusion Criteria : - Use High Dose Of Sedative Drug - Auto- Extubation

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqyatallah University of Medical Sinence

Street address

vanak-molasadra

City

tehran

Postal code

Approval date

2011-11-29, 1390/09/08

Ethics committee reference number

22-2249

Health conditions studied

1

Description of health condition studied

Patients in ICU

ICD-10 code

XXI

ICD-10 code description

XXI

Primary outcomes

1

Description

Lung Static Compliance

Timepoint

2 Time After Weaning Every 24 Hour

Method of measurement

Formula

Secondary outcomes

1

Description

Rapied shalow breathing index

Timepoint

2 time after weanning-evrey 24 hour

Method of measurement

Formula (f/tv)

Intervention groups

1

Description

The new index(iwi= compliance static*o2sat/(respiratory rate/tidal volume) Index measuring the isolation without physician is aware of its Doctor will measure current index Then the two methods in both sensitivity and specificity indices are compared. The range of each curve is determined and compared with the standard

and the doctor would have told

Category

Treatment - Other

2

Description

The physician After ensuring the correctness of the indexmeasures the index and then separates the patient from the machine

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqyatallah hospital

Full name of responsible person

Davood Tadrissi

Street address

Vanak - Mullasarda - Sheikh Bahai South

City

Tehran

2

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Davood Tadrissi

Street address

piroze-takhte-Three ways Takhti

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqyatallah University of Medical Sinence

Full name of responsible person

sohel najafe Mehre

Street address

Aghdaseah, Araj, Valayat

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Baqyatallah University of Medical Sinence

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

Baqyatallah University of Medical Sinence

Full name of responsible person

Davood Tadrissi

Position

Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqyatallah University of Medical Sinence

Full name of responsible person

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Web page address

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