Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessing the effects of Oxandrolone and Propranolole administration on improving post-burn hyper-metabolic changes

Protocol summary

Study aim
Assessing the effects of Oxandrolone and Propranolole administration on improving post-burn hyper-metabolic changes

Design
Clinical trial with control group, with parallel groups, randomized, with 768 patients. for randomization rand function of excel was used.

Settings and conduct
This study, will be performed with the aim of reduction in postburn hypermetabolic state in Velayat burn center in rasht, Guilan, as a double blinded randomized clinical trial. patients with inclusion criteria will enter the study and in 3 age groups of children, adults and elderly, will be candidate to receive oxandrolone and propranolol and similar placebo tablets. patients, researcher and data gatherers are blinded. statistical analyst is not blinded.

Participants/Inclusion and exclusion criteria
Severe burn injury, 0 to 80 years of age, negative pregnancy test in women, and informed consent.

Intervention groups
Control group: patients in age groups of children, adults and elderly are candidate to receive placebo similar to oxandrolone and propranolol tablets for a limited time.
Case group: patients in age groups of children, adults and elderly are candidate to receive oxandrolone and propranolol tablets for a limited time.

Main outcome variables
BMI; hepatic transaminase; White Blood Cells; Platelets; Blood Sugar; Length of Hospital Stay; Blood Pressure; Pulse Rate; Respiratory Rate; Number of Surgical Procedures, Number of Blood Products, Wrist/hip Ratio, Triceps Skinfold Thickness.

General information

Reason for update

Acronym
OxProp Study of Burns

IRCT registration information
IRCT registration number: **IRCT20210524051384N4**
Registration date: **2021-10-18, 1400/07/26**
Registration timing: **prospective**

Last update: **2021-10-18, 1400/07/26**
Update count: **0**

Registration date
2021-10-18, 1400/07/26

Registrant information

Name
mohammadreza mobayen

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2023-04-04, 1402/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the effects of Oxandrolone and Propranolole administration on improving post-burn hyper-metabolic changes

Public title
Oxandrolone and propranolole in burn patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Sever burn injury (TBSA>20%) aging 0 to 80 years Negative Pregnancy test in female patients of child bearing age Informed consent of patients entering the study
Exclusion criteria:
Not treated Malignancies, known history of AIDS and complex related diseases to AIDS and HIV. History of recent MI (Less than 6 weeks ago) Tuberose Sclerosis, Arthritis, Cirrhosis, Hyperlipidemia, Bone or Endocrine disorders, Autoimmune Diseases Long term consumption of corticosteroids or NSAIDS Diabetic Mellitus Prior to burn injury Renal failure (Creatinine level more than 3) Hepatic Disease (Bilirubin level more than 3) Anoxic Brain injury patients suffering from asthma and history of airway constriction
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **768**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, in each group, we will have randomization separately: In pediatric group: For randomization of treatment between groups, a randomized permutation block (4) method will be used. Considering the time of the sample's entry into the study and drug labeling (A and B, considering that the double-blind study is the only statistical analyzer informed of the type of allocated treatment) In adult group: For randomization of treatment between groups, permutation randomization block with size 4 will be used. Considering the time of the sample's entry into the study and drug labeling (A and B, considering that the double-blind study is the only statistical analyzer informed of the type of allocated treatment) In the elderly group: For randomization of treatment between groups, a randomized permutation block (4) method will be used. Considering the time of the entry of individuals into the study and drug labeling (A and B, considering that the double-blind study is the only statistical analyzer informed of the type of allocated treatment)
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, the drug manufacturer (AbuReihan Pharmaceutical Company) is requested to produce the drug and placebo in the same form and to distinguish between them only with labels A and B. Explain that each of the two types of drugs A and B are related to the desired treatment or placebo in a sealed envelope for researchers to send. The desired envelope will be provided to the statistics consultant. Accordingly, patients and the researcher who provides the drug to patients will be unaware of the type of drug. Medication and placebo in similar containers and forms will be delivered to patients at the time of admission as well as in each of the patient visit blocks.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences
Street address
Burn and Regerenative Medicine Research Center, Poursina four-way, Namjoo Street, Rasht, Guilan.
City
Rasht
Province
Guilan
Postal code
4193713194
Approval date
2021-05-05, 1400/02/15
Ethics committee reference number
IR.GUMS.REC.1400.056

Health conditions studied

1

Description of health condition studied
Burn Injury
ICD-10 code
X10
ICD-10 code description
Contact with hot drinks, food, fats and cooking oils

2

Description of health condition studied
Burn Injury
ICD-10 code

X00-X09

ICD-10 code description

قرار گرفتن در معرض دود، آتش و شعله

Primary outcomes

1

Description

Metabolic State of Burn Patient

Timepoint

In children group: on admission, on discharge, and 1, 2, 4. 6. 9 and 12 months after discharge. In adults group: on admission, on discharge and 40 days after discharge. In elderly Group: On admission and on discharge.

Method of measurement

Mercury sphygmomanometer, Caliper, Ruler, Scales, Laboratory tests.

Secondary outcomes

1

Description

weight

Timepoint

In children group: on admission, on discharge, and 1, 2, 4. 6. 9 and 12 months after discharge. In adults group: on admission, on discharge and 40 days after discharge. In elderly Group: On admission and on discharge.

Method of measurement

with scale , on kilogram

2

Description

BMI Changes

Timepoint

In children group: on admission, on discharge, and 1, 2, 4. 6. 9 and 12 months after discharge. In adults group: on admission, on discharge and 40 days after discharge. In elderly Group: On admission and on discharge.

Method of measurement

Based on weight and height

3

Description

wrist to hip ratio

Timepoint

In children group: on admission, on discharge, and 1, 2, 4. 6. 9 and 12 months after discharge. In adults group: on admission, on discharge and 40 days after discharge. In elderly Group: On admission and on discharge.

Method of measurement

using a centimeter stick

4

Description

Triceps Skinfold Thickness

Timepoint

In children group: on admission, on discharge, and 1, 2, 4. 6. 9 and 12 months after discharge. In adults group: on admission, on discharge and 40 days after discharge. In elderly Group: On admission and on discharge.

Method of measurement

Using a Caliper

5

Description

Hepatic transaminase

Timepoint

In children group: on admission, on discharge, and 1, 3, 6 and 12 months after discharge. In adults group: on admission, on discharge and 40 days after discharge. In elderly Group: On admission and on discharge.

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: At the beginning of the study, burn patients referred to the Burn and Regenerative research center of Velayat, according to age, are divided into 3 groups: children 0-18, adults (19-59) and the elderly (<60). Then each group in addition to receiving treatment the standard records recorded in the treatment protocols of burn patients will follow their own protocol during the study. The standard treatment for burn patients is as follows: At the time of admission, patients are admitted according to the American Burn Association (ABA) guidelines and undergo various treatments, including surgical treatment (including wound dressings, skin grafts, amniotic dressings, and other biological dressings. And supportive and non-surgical treatments (including antibiotic therapy, nutritional supplements, nutrition counseling, psychiatric counseling, physiotherapy and other rehabilitation programs). Pediatric group will enter the 7-block visits of a burn specialist.: Pediatric group in the age range of 0-18 years, with burns of 20% or more, is divided into 2 groups A (receiving medication) and group B (receiving placebo). The distribution of the drug is as follows: Group A, candidate for receiving oxandrolone and propranolol for 1 year after the occurrence of burns, is as follows: Oxandrolone: at a dose of 0.1 mg / kg, 2 times a day, orally, which is prescribed from the 5th day after the burn. (Propranolol dose is adjusted to reduce heart rate by 15%) In this visit, in addition to presenting the next visit plan, by encouraging the patient and his family and ensuring the patient's compliance in the use of drugs, the study participants are encouraged to continue the plan. The third block, on the 60th day After discharging. The patient is referred to the burn hospital of the provincial hospital and the following items are checked in him: Registration of vital signs including heart rate, respiration rate, blood pressure and body temperature, weight, BMI, Wrist / Hip ratio, triceps skinfold thickness. In this visit, in addition to presenting the next visit plan,

by encouraging the patient and his family and ensuring the patient's compliance with the medication, the study participants are encouraged to continue the plan. The 4th block is at the end of the 120th day after discharge, and the cases in the previous block are checked again during the visit to the burn and regenerative research center .The 5th block is done on the 180th day after discharge. The patient is referred to the burn and regenerative research center and the opposite cases are recorded in his file: blood sample for AST, ALT, CBC, vital signs including heart rate, respiration rate, blood pressure and body temperature, weight, BMI, Wrist ratio / Hip, Triceps skinfold thickness. In this visit, in addition to presenting the next visit plan, by encouraging the patient and his family and ensuring the patient's compliance with the medication, the study participants are encouraged to continue the plan. The 6th block is done on the 270th day after discharge. The patient was referred to the burn and regenerative research center and the cases in the previous block were re-examined. Block 7, which is the last block of the visit, the patient is referred to the burn and regenerative research center and the cases in block 5 are checked and registered again.

Category

N/A

2

Description

Control group: Group B is a candidate for Placebo, with a shape and size quite similar to oxandrolone and propranolol. In this way, at the beginning of hospitalization (block 0), demographic information, height, weight and all information related to burns (percentage, depth, mechanism, etc.) are recorded in the relevant questionnaire. From this time until the patient is discharged from the hospital, the above information, including vital signs on a daily basis, weekly weighing, blood sampling for AST, ALT, CBC and BS on the first, third and then weekly days, wound examinations for depth , degree, infection, blood supply, discharge, color and eclipse status are recorded when changing dressings. The next block (block 1) is related to the time of discharge, when the patient is discharged with the necessary knowledge, training and recommendations, nutritional advice to continue a high-protein diet, and a 7-day visit plan. In this block, information such as number of days of hospitalization, number of days in need of respiratory support, number of days of hospitalization in ICU, number of surgical procedures, amount of skin graft used in surgery, proportion of burn area, incidence of infection, number of blood and blood products used at the time of admission (including Platelet, PC, and FFP), weight, BMI, Wrist / Hip ratio, Triceps skinfold thickness are recorded in the questionnaires. The second block is on the 30th day after discharge when the patient refers to the burn and regenerative research center and the following cases are recorded in his file: blood sample for AST, ALT, CBC, vital signs including heart rate, number respiration, blood pressure and body temperature, weight, BMI, Wrist / Hip ratio, triceps skinfold thickness.

Category

N/A

3

Description

Intervention group: Adults in the age group of 19 to 59 years, with burns of 20% or more, are divided into two groups A (receiving medication) and group B (receiving placebo). How to distribute the drug is as follows: Group A candidates for oxandrolone and propranolol for 4 weeks after discharge are as follows: Oxandrolone: 10 mg twice daily, orally, given 2-3 days after burn injury. Propranolol: At a dose of 3.3 mg / kg daily, orally, which is prescribed from day 2 after burn injury.

Category

N/A

4

Description

Control group: B Group B, which is a candidate for Placebo, with a shape and size quite similar to oxandrolone and propranolol. After entering the study and prescribing the drug and placebo to them, the adults enter the dual block program of the doctor's visits. At the beginning of hospitalization (block 0), demographic information, height, weight and all information related to burns (percentage, depth, mechanism, etc.) are recorded in the relevant questionnaire. From this time until the patient discharge from the hospital, the above information including vital signs on a daily basis, weekly weighing, taking blood samples to check AST, ALT, CBC and BS on the first, third and then weekly days, wound examinations in terms of depth, degree, infection, blood flow, discharge, color and condition are recorded when changing dressings. The next block (block 1) is related to the time of discharge, when the patient is discharged with the necessary knowledge, training and recommendations, nutritional advice to continue a high-protein diet, and a dual visit plan. In this block, information such as number of days of hospitalization, number of days in need of respiratory support, number of days of hospitalization in ICU, number of surgical procedures, amount of eclipse used in surgery, proportion of burn area, incidence of infection, number of blood and Blood products used at the time of admission (including Platelet, PC, and FFP), weight, and BMI are recorded in questionnaires. Block 2, which is on the 30th day after discharge, the patient is referred to the burn ward of the provincial hospital and the above items are checked in him: blood sample to check AST, ALT, CBC, recording vital signs including heart rate, respiratory rate, Blood pressure and body temperature, weight, BMI.

Category

N/A

5

Description

Intervention group: Elderly group: The elderly group in the age range of 60 years and older, with burns of 20% or more, are divided into two groups A (receiving

medication) and group B (receiving placebo).How to distribute the drug is as follows: Group A candidates for oxandrolone until discharge are as follows: Oxandrolone: 10mg, twice daily, orally, starting at the time of admission and continuing until discharge. After entering the study and prescribing the drug and placebo to him, at the beginning of hospitalization (block 0), demographic information, height, weight and all information related to burns (percentage, depth, mechanism, etc.) are recorded in the relevant questionnaire. From this time until the patient is discharged from the hospital, the above information, including vital signs on a daily basis, weekly weighing, blood sampling for AST, ALT, CBC and BS on the first, third and then weekly days, depth examinations of the wound the degree, infection, blood supply, discharge, color and condition of the eclipse are recorded when changing dressings. The next block (block 1) is related to the time of clearance. In this block, information such as number of days of hospitalization, number of days in need of respiratory support, number of days of hospitalization in ICU, number of surgical procedures, amount of eclipse used in surgery, relation to burn area, incidence of infection, number of blood and Blood products used at the time of admission (including Platelet, PC, and FFP), weight, and BMI are recorded in questionnaires.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat Burn Center

Full name of responsible person
Mohammadreza Mobayen

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Velayat Hospital, Namjoo Street, Rasht, Guilan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
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Web page address

Grant name

Grant code / Reference number
Vice-Chancellor for Research, Guilan University of Medical Sciences

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

Title of funding source
Rasht University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Rasht University of Medical Sciences

Full name of responsible person
Zahra Haghani

Position
General Practitioner

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Person responsible for updating data

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

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available