

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Parenteral albumin therapy in patients with extensive Burn

Protocol summary

Summary

Burn resuscitation and its management is the area of great controversies and among these, there is a continuing challenge about albumin administration and its beneficial or detrimental effect on mortality, multi organ failure, edema, wound healing and hospital stay. We designed a new study in our burn center for evaluation of albumin administration effects on burn wound healing, hospital stay duration, weight change and mortality. From January 2005 to May 2007, 140 adult female patients with 20% to 40% TBSA burn admitted in Ghotbeddin burn hospital in Shiraz were randomized into two groups, using random allocation software. Patients with respiratory burn were excluded. First group received high protein diet and second group received intravenous albumin supplementation of 20% albumin solution form a single provider company with amount of 1 gr/kg/day after the first 24 hours of burn in addition to high-protein diet. Patients who developed severe hypoalbuminemia (serum albumin <1.5gr/dl) in control group, were excluded from the study and IV albumin supplement started for them. Weight, serum albumin, serum total protein and transferrin levels were checked for the patients at second day of hospitalization (before starting IV albumin) and then weekly to the end of hospitalization. Healing time considered the length of time needed to the wound surface be ready for graft or completely healed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802141605N3**

Registration date: **2009-05-16, 1388/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-05-16, 1388/02/26

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research

Expected recruitment start date

2005-01-01, 1383/10/12

Expected recruitment end date

2007-06-30, 1386/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Parenteral albumin therapy in patients with extensive Burn

Public title

Parenteral albumin therapy in patients with extensive Burn

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: adult female patients with 20% to 40% TBSA burn
Exclusion criteria: Presence of multiple trauma, presence of comorbid diseases, presence of

significant inhalation injury, need to intensive care

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

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

Shiraz University of Medical Sciences,Ghotb-eddin
Burn Center

Street address

Fakhrabad Street, Shiraz

City

Shiraz

Postal code

71638-54733

Approval date

2007-02-05, 1385/11/16

Ethics committee reference number

CT-86-2363

Health conditions studied

1

Description of health condition studied

Effect of albumin on burn wound healing

ICD-10 code

E64.0

ICD-10 code description

Sequelae of protein-energy malnutrition

Primary outcomes

1

Description

Length of hospital stay

Timepoint

weekly to the end of hospitalization

Method of measurement

Number of admission days

2

Description

Weight change

Timepoint

weekly to the end of hospitalization

Method of measurement

Percentage of change in patient's weight

3

Description

Healing time

Timepoint

weekly to the end of hospitalization

Method of measurement

Time needed to more than 80% of the wound surface be
ready for graft or completely healed

Secondary outcomes

empty

Intervention groups

1

Description

Intravenous albumin supplementation of 1 gr/kg/day,
20% albumin solution after the first 24 hour of burn in
addition to high-protein diet

Category

Other

2

Description

High protein diet

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghotb-eddin Burn Center

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research

Full name of responsible person

Mohammad Hossein Dabbaghmanesh

Street address

Vice-chancellor for Research

City

Shiraz

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

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

Assistant Professor, General Surgeon

Full name of responsible person

Ali Akbar Mohammadi

Position

Shiraz University of Medical Sciences

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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