# The biological dressing and conventional treatment in patients with massive burn: a clinical trial

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
17/08/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/09/2006	Completed  Condition category	[X] Results		
Last Edited		Individual participant data		
07/01/2021	Injury, Occupational Diseases, Poisoning			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

### Protocol serial number

289-zanjan university of medical sciences

# Study information

#### Scientific Title

The biological dressing and conventional treatment in patients with massive burn: a clinical trial

### **Acronym**

Biological dressing study

## **Study objectives**

Due to less experience in use of biological dressing in the developing country, the aim of this study was to compare the outcome of biological dressing and conventional treatment in patients with massive burns.

## Ethics approval required

Old ethics approval format

# Ethics approval(s)

This study was approved by the ethics committee of Zanjan University of Medical sciences (2003) and all patients gave informed consent before entering into the study.

## Study design

Non randomised controlled trial

### Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Burns

#### Interventions

The patients were divided into two groups:

- 1. Those in the first group (conventional treatment) did not have satisfying wounds for treatment with biological dressings. This group were treated by daily washing, removal of loose dead tissue and topical application of saline soaked dressing. When the granulating bed became free of debris and uninfected, Split Thickness Skin Grafts (STSG) were applied usually after two to eight weeks.
- 2. The second group (biological dressings) had wounds that were satisfying and interesting for treatment with biological dressing (xenoderm). Xenoderm is a lyophilised pig skin, manufactured by MBP (Medical Biomaterial Product, Germany). First, xenoderm was prepared in normal saline solution and after debridement of the burned place with dermatome (tangential excision) and rinsing the wound with normal saline, xenoderm was placed on the wound by the surgeon (the author and colleagues) and fixed using suture, dressing or bandage and the organ immobilised by splint if necessary. Twenty four hours after surgery, dressing was opened. For full thickness area after two to eight weeks xenoderm was removed and STSG was performed. All patients received cefazolin prophylaxes.

### Intervention Type

Other

#### Phase

**Not Specified** 

## Primary outcome(s)

- 1. Mechanism of injury
- 2. TBSA
- 3. Total hospital stay
- 4. Amount of serum until started per oral feeding use
- 5. Number of oral or injectable analgesic intake
- 6. The number of dressing association with inhalation injury
- 7. Mortality

## Key secondary outcome(s))

Albumin and Fresh Frozen Plasma (FFP) intake.

### Completion date

30/07/2006

# **Eligibility**

## Key inclusion criteria

The patients had Total Body Surface Area (TBSA) between 30% to 75% due to scalds or flames.

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

### Age group

**Not Specified** 

### Sex

**Not Specified** 

### Total final enrolment

118

# Key exclusion criteria

Non-infected and non-chemical burns.

### Date of first enrolment

01/10/2002

# Date of final enrolment

30/07/2006

# Locations

### Countries of recruitment

Iran

Study participating centre Shafieyeh Hospital Zanjan Iran 45138

# Sponsor information

## Organisation

Zanjan University of Medical Sciences (Iran)

### **ROR**

https://ror.org/01xf7jb19

# Funder(s)

# Funder type

University/education

### **Funder Name**

A grant from Zanjan University of Medical Sciences (Iran)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2009	07/01/2021	Yes	No