

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

Submission date

17/08/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

25/09/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/01/2021

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Seyednejat Hosseini

Contact details

Shafieyeh Hospital

Karagran St

Zanjan

Iran

45138

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nejat.hosini@zums.ac.ir

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Albumin and Fresh Frozen Plasma (FFP) intake.

Overall study start date

01/10/2002

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

118 burns' patients

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)

Sponsor details

Azadi Blvd

Zanjan

Iran

45154

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nejat.hosini@zums.ac.ir

Sponsor type

University/education

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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