ISRCTN01055688 https://doi.org/10.1186/ISRCTN01055688

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

Submission date
17/08/2006

Recruitment status
No longer recruiting

Registration date
25/09/2006

Overall study status
Completed

Last Edited
07/01/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
-
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
-
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