ISRCTN14797020 https://doi.org/10.1186/ISRCTN14797020

Comparison of microbial cellulose to silver based burn dressing intreatment of superficial burns

Submission date
05/09/2017

Recruitment status
No longer recruiting

Registration date
06/11/2017

Overall study status
Completed

Last Edited
17/07/2018

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Burns in general are divided into superficial (surface) and deep injuries. Deep burns generally require operation and skin transplantation. Superficial burns are treated conservatively with wound care procedures until the wound has healed. The treatment with silver sulphadiazine cream, which has been used as standard for superficial burns, needs frequent change of dressings, which in turn requires time and effort, and is cumbersome for the patient as well as health care providers. Besides that, some studies have shown that the toxicity of silver can delay wound healing. The search for dressing materials that can avoid these disadvantages is important. One alternative is the microbial cellulose dressing material, which has shown promising results regarding reduced pain and fewer dressing changes compared with silver-sulfadiazine treatment, also reporting no irritation or allergy, and with no bacterial presence. However, so far there have been too few studies to fully rely on these favourable results. The aim of this study is to evaluate if the use of microbial cellulose (eiratex) dressing for superficial (partial thickness) burns would result in better outcome compared to standard of care (silver sulphadiazine 1% cream) dressings in terms of healing time, infection rate, hospital stay, pain scoring, and less frequent dressing changes.

Who can participate?
Patients aged five and older who have a burn.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their burns cleaned with normal saline (salt and water). Microbial cellulose sheets are applied under aseptic conditions and are covered with an adhesive plastic film and a bandage is applied. Every third day the final elastic bandage is removed and the cellulose is inspected. Those in the second group are cleaned with normal saline and have a silver sulphadiazine cream is applied to the burn and covered with gauze. This is changed on a regular basis during each wound care visit every second to third day. Participants are followed up to assess the amount of time, dressing changes, rate of infections during the hospital stay.

What are the possible benefits and risks of participating?
Participants may benefit from a more favourable outcome (compared with the other group) regarding healing time, infection rate, hospital stay, pain scoring and less frequent dressing changes.
In general, patients with burns are susceptible for wound infections, which can be followed by complications such as sepsis (blood-poisoning) and organ dysfunction, particularly among patients with large and deep burns. The participants taking part in the study were not exposed to risks beyond that of the being burned and receiving standard treatment. The participants taking part in the study were not paid or otherwise compensated for their participation.

Where is the study run from?
Suez Canal University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
January 2014 to October 2016

Who is funding the study?
Suez Canal University (Egypt)

Who is the main contact?
Dr Ahmed Abo-Elnaga
moustafa.elmasry@liu.se

Contact information

Type(s)
Scientific

Contact name
Dr Ahmed Abo-Elnaga

Contact details
Surgery Department
Plastic Surgery Unit
Suez Canal University Hospital
Ring Road
Ismailia
Egypt
41111
+20 643 230539
ahmed.naga2000@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MC001

Study information

Scientific Title
Microbial cellulose dressing for partial thickness burns compared to treatment with silver sulphadiazine, a prospective randomised clinical trial

Study objectives
The use of microbial cellulose dressing results in better outcome compared to silver sulphadiazine dressings in terms of healing time, frequency of dressing change, infection rate, hospital stay and pain scoring.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Suez Canal University Faculty of Medicine, Research Ethics Committee, 21/09/2014

Study design
A prospective randomised clinical trial with two Groups (study and Control Group)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (in Arabic)

Health condition(s) or problem(s) studied
partial thickness burns

Interventions
The patients are recruited at the trial site. Those who are eligible according to the inclusion criteria were informed about the study, given the opportunity to ask questions to the investigator, and if they were willing to participate they were asked to sign the written informed consent.

The following data is documented during the first day: age, sex, percentage total body surface area burned (TBSA%), percentage superficial and deep dermal body surface area burned (BSA%), location on the body, burn mechanism, medical history, a baseline photograph of the burn

wound, assessment of pain by the Face, Legs, Activity, Cry, Consolability (FLACC) scale during wound care procedure and after it.

Participants are randomly allocated to one of two groups: the study group (microbial cellulose) and control group (standard of care). Block randomization with 20 patients for each group was used with random allocation of the individuals into each group.

The study group (microbial cellulose): The burn wounds are cleaned with normal saline and any bullae or debris are removed. Microbial cellulose (eiratex) sheets (Epiprotect® S2Medical AB, Sweden) are applied under aseptic conditions, and covered with an adhesive plastic film. A final elastic bandage is applied. Every third day the final elastic bandage is removed and the cellulose dressing is inspected through the plastic film. In case of partial detachment from the wound, or presence of signs of infection, the cellulose should be replaced by a new sheet.

The control group (silver sulphadiazine cream 10mg/g was used as a standard of care): The burn wounds are cleaned with normal saline and any bullae or debris were removed. Silver sulphadiazine cream 10 mg/g (1%) (Dermazine®) are applied under aseptic conditions, covered with sterile gauze, and a final elastic bandage is applied. Silver sulphadiazine is changed on regular basis during each wound care procedure / visit, every second to third day.

The burn wounds are cleaned by the attending surgeon. The dressing material is put on by the attending surgeon. The evaluations are done by the attending surgeon. The attending surgeon is a specialist in plastic surgery, with expertise in burn care by experience of 2-6 years work at the burn centre. The intervention was delivered in daily clinical practice. Hands on. Face to face. The intervention occurrs at the trial site which was the Burn Unit in Plastic Surgery department, in a University Hospital. The necessary infrastructure was that of a specialised burn centre.

The whole wound care procedure was done at admission. The following every third day the final elastic bandage was removed and the cellulose dressing was inspected through the plastic film. In case of partial detachment from the wound, or presence of signs of infection, the cellulose should be replaced by a new sheet. In the control group the dressing was changed on regular basis during each wound care procedure / visit, every second to third day.

The study outcome measures of duration of time, number of dressing changes, and rate of infection, are evaluated for each patient at the end of the duration of hospital stay or time until epithelization, whichever had the longer duration. During the subsequent wound care procedures / visits, evaluation is done by the attending surgeon: photograph of the burn wound, presence of clinical signs of infection, assessment of presence of bleeding or exudate, and assessment of pain by the FLACC scale. End of treatment was declared when healing had occurred, evaluation was done by the attending surgeon, follow up photograph of the wound area, and assessment of pain by the FLACC scale. Other variables registered during the study period were: surgery details, healing time, duration of hospital stay.

The attending surgeon is responsible for the adherence to intervention and the study case report form (CRF), as well as responsible for decisions regarding change in treatment strategy in case of medical reasons. The CRF is the primary data collection instrument for this study. All data requested on the CRF is to be recorded and all missing data had to be explained. There is no external monitor responsible for the assessment.

Intervention Type
Other

Primary outcome measure
Burn wound healing time is measured using the difference between the date of admission and the first date at which the evaluation done by the attending surgeon can verify that the wound is epithelialised at each wound care procedure, the difference between the dates is calculated as number of days at the end of the study.

Secondary outcome measures
1. Rate of infection is measured using the number of patients in each group who showed presence of clinical signs of infection. Evaluation is done and recorded at each wound care procedure, the calculation of rate (the number of patients with signs of infections in one group /total number of patients in that group) is done at the end of the study.
2. Duration of hospital stay is measured using the difference between the date of admission and that of discharge from the hospital. The dates are recorded prospectively and the difference is calculated as number of days at the end of the study.
3. Pain scoring during and after dressing change is measured using the pain assessment scale Face, Legs, Activity, Cry, Consolability (FLACC) at each wound care procedure, and it is recorded prospectively.
4. Number of dressing changes needed is measured using the sum of total number of dressing changes required for each patient during the time between the date of admission and the date of wound healing. Each dressing change is recorded prospectively; the sum is calculated at the end of the study

Overall study start date
01/01/2014

Completion date
30/10/2016

Eligibility

Key inclusion criteria
1. Thermal injury of any aetiology
2. Superficial or deep partial thickness burn
3. Recent burn (within the first 72 hours)
4. Aged 5 years or more.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
40 patients

Key exclusion criteria

1. Children younger than 5 years
2. Full thickness burn regardless of the percentage of burn
3. Pregnant or breast feeding women

Date of first enrolment
01/10/2014

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
Egypt

Study participating centre
Suez Canal University Hospital
Ring Road
Ismailia
Egypt
41111

Sponsor information

Organisation
Suez Canal University Hospital

Sponsor details
Surgery Department
Ring Road
Ismailia
Egypt
41111

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02m82p074

Funder(s)

Funder type
University/education

Funder Name
Suez Canal University

Results and Publications

Publication and dissemination plan
Planned for publication fall 2017-spring 2018. No additional documents will be available, the intended publication date will occur soon.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The participant level data consists of anonymous numbers in a data sheet, which is stored within the data security system of the hospital where the researchers are working. There is no web link available as the security system does not allow external visitors. The process for requesting access can be initiated by the use of the contact details below. Consent from participants was obtained for publication of the analysed results of the study. No consent was obtained for distributing individual data to external interests.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018		Yes	No