ISRCTN79764413 https://doi.org/10.1186/ISRCTN79764413

Efficacy of silver zinc sulfadiazine cream containing silk sericin for the treatment of burn wounds

Submission date
21/05/2012

Recruitment status
No longer recruiting

Registration date
28/05/2012

Overall study status
Completed

Last Edited
23/09/2016

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Second-degree burns affect the epidermis and the dermis (lower layer of the skin). They cause pain, redness, swelling, and blistering. Sericin is a protein created by silkworms in the production of silk, which has been found to promote wound healing. The aim of this study is to assess the effectiveness of a silver zinc sulfadiazine (antibiotic) cream with added sericin for the treatment of patients with second-degree burn wounds.

Who can participate?
Patients aged 15-60 with second-degree burn wounds

What does the study involve?
Participants undergo an initial assessment including demographic information, medical and social history, and an assessment of the burn injury with photographs. On the day of admission, body temperature recordings and blood samples are taken from all participants to determine the possibility of infection, as well as liver and kidney function. Body temperature recordings and blood tests are repeated on days 7, 14 and 28 after admission. The extent of the burn injuries is determined. Participants are then randomly allocated to be treated with either silver zinc sulfadiazine cream or silver zinc sulfadiazine cream containing sericin. All participants are treated with fluid replacement with daily dressing changes and topical cream treatment during their period of hospitalization. After admission, the wounds are cleaned with normal saline (salt) solution and the cream is directly applied to the wound. The dressing is changed and the cream is applied once daily. Treatment is continued until the wounds are completely healed. A wound swab is taken after 2 weeks. The wound is checked at each dressing change for signs of infection and healing by expert surgeons. The length of time to heal is also recorded and side effects, if any, are assessed. Pain is assessed in all participants every 7 days 30 minutes after a dressing change. Burn health status is also evaluated.

What are the possible benefits and risks of participating?
Participants may benefit from faster wound healing and better quality of life but may experience side effects from silk sericin.

Where is the study run from?
Mahidol University (Thailand)

When is the study starting and how long is it expected to run for?
September 2010 to August 2011

Who is funding the study?
National Research Council (Thailand)

Who is the main contact?
Associate Professor Pornanong Aramwit

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03/55

Study information

Scientific Title
Efficacy of silver zinc sulfadiazine cream containing silk sericin for the treatment of burn wounds: a randomized controlled trial

Study objectives

1. Silver zinc sulfadiazine cream containing silk sericin is more efficient than silver zinc sulfadiazine cream alone in patients with second degree burn wounds.
2. Silver zinc sulfadiazine cream containing silk sericin is safe for the treatment of second degree burn wounds.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board Committee, Mahidol University, 23/09/2010, ref: 301/2553 (EC1)

Study design
Randomized double-blind placebo-controlled experimental study

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Second degree burn wounds

Interventions
After eligibility was established, an initial evaluation was performed on each patient that included recording subject demographics, medical and social history, and a baseline assessment of the burn injury with photographic documentation. On the day of admission, body temperature and blood samples were taken from all patients to determine the possibility of infection, as well as liver and renal functions, blood glucose, electrolytes, blood counts, albumin level, and blood gases. Body temperature recording and the same blood examinations were repeated on days 7, 14 and 28 after admission. Total body surface area standard formulae were provided and used to determine the extent of the burn injuries.

Patients were then randomly assigned to a care protocol that included either silver zinc sulfadiazine cream (control) or silver zinc sulfadiazine cream containing sericin (treatment); the physician investigators and other medical personnel were blinded to the type of treatment from the first day of admission until the wounds were completely healed. All patients were treated with fluid resuscitation and fluid replacement according to the Parkland formula, with daily dressing changes and topical cream treatment during their period of hospitalization. After admission, the wounds were cleaned with normal saline solution and the topical agent (either

silver zinc sulfadiazine cream or silver zinc sulfadiazine cream containing sericin) was directly applied to the wound. The dressing was changed and the creams applied once daily. Treatment with the topical agents was continued until the wounds were completely healed and epithelialized. A wound swab culture was taken after 2 weeks. The wound was clinically observed at each dressing change for signs of infection and the size as well as the nature of epithelialization by expert surgeons. The wound size was measured using Visitrak Digital and the healing percentage of the wound was calculated. The length of time to heal was also recorded and adverse drug reactions, if any, were assessed using Naranjos algorithm.

Pain was assessed in all patients every 7 days using the visual analog scale 30 min after a dressing change. Burn health status was also evaluated using Burn-Specific Health Scale-Brief (BSHS-B) with slight modifications.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The wound size was measured using Visitrak Digital and the healing percentage of the wound was calculated. The length of time to heal was also recorded.

Secondary outcome measures
1. Adverse drug reactions were assessed using Naranjos algorithm
2. Pain was assessed in all patients every 7 days using the visual analog scale 30 min after a dressing change
3. Burn health status was also evaluated using Burn-Specific Health Scale-Brief (BSHS-B)

Overall study start date
01/09/2010

Completion date
30/08/2011

Eligibility

Key inclusion criteria
1. 15-60 years of age
2. Second degree burn wounds covering no less than 15% of the total body surface area (TBSA) with no wound infection
3. Patients were to stay at the hospital until the wounds were completely healed

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
16 patients

Key exclusion criteria
1. Patients with history of allergy to sulfonamides, sericin, or any of the other ingredients in the formulation
2. Patients who had active diabetes mellitus, chronic obstructive pulmonary disease, psychological problems, dementia, malnutrition or immunodeficiency
3. Patients who experienced abnormal liver or renal function tests prior to enrollment
4. Patients with cancer or receiving chemotherapy and those who were pregnant or breastfeeding
5. Patients who show no response to the treatment, were not willing to continue with the study, or when the physician opined that treatment was no longer needed

Date of first enrolment
01/09/2010

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
Thailand

Study participating centre
Chulalongkorn University
Bangkok
Thailand
10330

Sponsor information

Organisation
National Research Council (Thailand)

Sponsor details
196 Paholyotin Road
Chatuchak
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10900

Sponsor type
Research council

Website
http://www.nrct.go.th/

ROR
https://ror.org/018wfhg78

Funder(s)

Funder type
Research council

Funder Name
National Research Council (Thailand) ref: 2554-21

Alternative Name(s)
National Research Council, Consiglio Nazionale delle Ricerche (IT), National Research Council of Italy, National Research Council (Italy), Italy, Consiglio Nazionale delle Ricerche, CNR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

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