

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	☐ Prospectively registered
		☐ Protocol
Registration date 28/05/2012	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 23/09/2016	Condition category Injury, Occupational Diseases, Poisoning	☐ 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

Contact name
Dr Pornnaong Aramwit

Contact details
Chulalongkorn University
Department of Pharmacy Practice
Faculty of Pharmaceutical Sciences
254 Payathai Road
Bangkok
Thailand
10330

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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), The National Research Council (Cnr), National Research Council of Italy, National Research Council (Italy), Italy, Consiglio Nazionale delle Ricerche, CNR

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary