

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

<b>Submission date</b> 21/05/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 23/09/2016	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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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

Bangkok

Thailand

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