

# Debridement options for the treatment of the forearm and hand partial thickness dermal burns

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 16/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 16/12/2016	<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

Debridement is the medical removal of dead, damaged, or infected tissue to improve the healing potential of the remaining healthy tissue. Many studies show that debridement is essential for the proper wound healing process. Leaving necrosis (dead tissue) and debris in the wound can lead to the wound not healing and becoming chronic. Many studies demonstrate the advantage of early surgical debridement and grafting (transplantation of skin). Surgical removal of dead tissue of partial thickness burns, especially in the forearm and hand regions, should be performed extremely carefully. Moreover, surgery reduces the chances of the burn wound healing itself (self-epithelialization) and has a high risk of serious complications (massive bleeding, damage to blood vessels and nerves). The aim of this study is to compare non-surgical debridement methods for the treatment of forearm and hand partial thickness burns.

### Who can participate?

Patients aged from 18 to 65 with forearm and hand deep dermal partial thickness burns (a burn that affects the top two layers of skin)

### What does the study involve?

Participants are randomly allocated into four groups. The first group receives standard treatment with gauze dressings with silver sulfadiazine ointment. The second group is treated with hydrocolloid dressings which promotes the shedding of dead tissues (autolytic debridement). The third group is treated with dressings with silver sulfadiazine cream and mechanical debridement (physically removing dead tissue) with special single-use pads. The fourth group is treated with an enzyme gel on gauze dressings to remove dead tissue (enzymatic debridement). The duration of all treatments is three weeks (21 days). An assessment is organized after six months to assess scarring.

### What are the possible benefits and risks of participating?

Participants receive modern non-surgical treatment methods that are less painful and more convenient. Some burn wounds could heal after three weeks. Burn wounds which take longer than 21 days to heal may scar.

Where is the study run from?  
Lithuanian University of Health Sciences Kaunas Clinics (Lithuania)

When is the study starting and how long is it expected to run for?  
April 2014 to February 2017

Who is funding the study?  
Biocentras (Lithuania)

Who is the main contact?  
Ernest Zacharevskij  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
FMAN-01

## Study information

**Scientific Title**  
Comparison of enzymatic, mechanical and autolytic debridement methods efficiencies for the treatment of the forearm and hand deep dermal burns

**Acronym**  
EMANAM (Enzymatic, Mechanical and Autolytic Necrectomy for Ambustum Manus)

**Study objectives**  
To compare enzymatic, mechanical and autolytic debridement methods for treatment of the forearm and hand deep dermal partial thickness burns.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Kaunas regional biomedical research ethics committee, 07/01/2014

**Study design**

Randomized controlled parallel-group single-center clinical trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Forearm and hand deep dermal partial thickness burns

**Interventions**

Participants are randomised into four treatment groups:

1. Standard treatment – gauze dressings with silver sulfadiazine (SSD) 1% ointment (Sulfargin, Grindeks AS, LV) applied once daily on burn wounds
2. Hydrocolloid dressings (GranuFlex®, ConvaTec, USA) changed every 3 days which promote autolytic debridement
3. Dressings with silver sulfadiazine 1% cream once daily and mechanical debridement with special single-use pad of monofilament polyester fibers (Debrisoft, Lohmann & Rauscher GmbH & Co, G,A) for the first four to five days once daily
4. Proteolytic enzyme complex gel (Streptomyces flavus 197 Ferment, Biocentras, LTU) on gauze dressings once daily

The duration of all treatments was three weeks (21 days). If this process overstepped 21 days, late grafting would be intended to heal residual parts of the wound. An assessment was organized after six months to evaluate post-burn scars.

**Intervention Type**

Other

**Primary outcome(s)**

Measured at 3, 7, 14 and 21 days post burn:

1. Burn wound size, estimated by covering it with transparent film and counting square centimeters with a ruler
2. Pain, measured with the Visual Analog Scale (VAS) 10 minutes after dressings have been changed
3. Clinical wound conditions: persistence of necrosis, amount of fibrin, granulation tissue, and epithelialization process, evaluated as a percentage from whole wound area by the same physician according to the study protocol measurement parameters
4. Burn wound contamination, assessed using the Levine wound-swabbing technique

**Key secondary outcome(s))**

Measured at six months follow-up:

1. Quality of post burn scars, assessed using the Vancouver Scar Scale (VSS)
2. Functional recovery, assessed using the Disabilities of the Arm, Shoulder and Hand (DASH) outcome measure official Lithuanian translation

**Completion date**

01/02/2017

## **Eligibility**

**Key inclusion criteria**

1. Patients aged from 18 to 65
2. Non-extensive burns (total body surface area, TBSA <30%)
3. Forearms and hands deep dermal partial thickness burns (2B°, LDI evaluation: 260 - 600PU)
4. Agreed with trial protocol and signed the consent form

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients with superficial partial thickness and full thickness forearms and hands burns (2A°, 3°; LDI evaluation: <260PU, >600PU)
2. Patients with known pregnancy (pregnancy test was performed for all female patients)
3. Vulnerable persons (psychiatric diagnosis)

**Date of first enrolment**

01/04/2014

**Date of final enrolment**

01/08/2016

## **Locations**

**Countries of recruitment**

Lithuania

**Study participating centre**  
**Lithuanian University of Health Sciences Kaunas Clinics**  
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## Sponsor information

**Organisation**  
Biocentras

**ROR**  
<https://ror.org/005gk6w44>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Biocentras

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are available from Ernest Zacharevskij  
([ernest.zacharevskij@gmail.com](mailto:ernest.zacharevskij@gmail.com)) on reasonable request

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes