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

Submission date
12/12/2016

Recruitment status
No longer recruiting

Registration date
16/12/2016

Overall study status
Completed

Last Edited
16/12/2016

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
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?
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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) on reasonable request

IPD sharing plan summary
Available on request