A prospective, randomized, controlled trial of negative-pressure wound therapy use in conflict-related extremity wounds

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Research protocol

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Trial location
Médecins Sans Frontières/Doctors Without Borders (MSF) is one of the worlds leading independent organizations for medical humanitarian aid. MSF conducts an emergency trauma project in the Ministry of Health hospital in Ar Ramtha, Jordan, less than five kilometers **from the border with Daraa governorate in Syria. A majority of patients within the project receive treatment for blast- and gunshot-related trauma wounds originating from the Syrian armed conflict.** Discharged patients are sometimes continuously treated by MSF in Zaatari refugee camp. **Within the** MSF Ar Ramtha **project wound management has been difficult, often complicated by infection and antibiotic resistance. A need for wound therapy alternatives better than the conventional wound dressing method currently used has been identified.**

Background
Extremity wounds and fractures constitute the majority of conflict-related traumatic injuries, both for civilians and combatants . Conflict-related injuries often result in soft and boney tissue being contaminated with foreign material, generally leading to secondary infection . **Negative-pressure wound therapy (NPWT) is widely used in the treatment of wounds and is considered to promote wound healing and prevent infectious complications. The technique involves the application of a wound dressing through which a negative pressure is applied. Any wound and tissue fluid** is **drawn away from the area** and~~is~~ **collected into a canister. Due to a plastic film overlaying the wound the risk of wound contamination is reduced. NPWT is supported for use in a range of surgical applications, including after or in between debridements as a bridge to definite closure of soft tissue wounds . The technique has previously been used in the treatment of acute conflict-related wounds with satisfactory results .**

Cochrane reviews of NPWT for the treatment of chronic wounds and surgical wounds were inconclusive due to the lack of suitably powered, high-quality trials. A recent systematic review of randomized, controlled trials (RCTs) of NPWT for the treatment of acute and chronic wounds concluded there is a lack of evidence and that good RCTs are needed . For the use in limb trauma, NPWT is considered suitable for complex soft tissue injuries . NPWT appears to be an effective and safe adjunctive treatment of high-

energy combat wounds but existing results are retrospective and lack follow-up . The support of RCTs is needed to establish best treatment strategies.

Summary of potential risks and benefits

Both treatment methods (NPWT and conventional dressings) are well established and used in Jordan for the treatment of acute and chronic wounds. As neither of the two treatment modalities are known to be better in terms of outcome neither patient group may be regarded as receiving preferential treatment. NPWT is generally considered a safe treatment method. Potential benefits are shortened healing time and fewer infectious complications. Potential risks are pain, mainly associated with dressing changes and bleeding, predominantly minor bleeding from granulation tissue .
Conventional wound dressing has the potential benefit of being a safe treatment method used for many years. Since this method permits air into the wound there is a potential risk of contamination and the development of wound infection.

Objectives

We aim to evaluate the ~~role~~ efficacy and safety of NPWT in the treatment of traumatic extremity wounds in a context associated with a high level of contamination and infection.

Design

Study description

A prospective, randomized, controlled trial comparing NPWT to conventional dressing methods in the treatment of conflict-related extremity wounds.

Study period

Two year study period. May 2015 to May 2017.

Recruitment and eligibility

Recruitment methods

Patients will continuously be included as they present at the emergency department of the hospital in Ar Ramtha.

Information for patients and consent

Written and oral information in English and Arabic will be given to eligible participants. English versions of the participation information sheet and the consent form are provided as appendices to this document. Participants will be informed regarding their right to withdraw from the study and issues concerning confidentiality and the information sheet will remain with the participant. No incentives or inducements will be provided to any participant. Written informed consent before randomization or delayed consent within five days of randomization will be collected from each patient who agrees to be included.

The principle of delayed consent is an established principle in trials that include critically ill patients and is considered acceptable from research participants' perspectives . Due to the nature of the study setting patients will be transported from the emergency room to the operative theatre for emergency surgery, often without full consciousness. The emergency circumstances require prompt action and generally

provide insufficient time and opportunity to locate and obtain consent from each subject's legally authorized representative. The research therefore could not be practically carried out without the use of delayed consent. The two treatment methods of the study are both well established and used in Jordan for the treatment of acute and chronic wounds. The methods are not associated with any serious risks. As neither of the two treatment modalities are known to be better in terms of outcome neither patient group may be regarded as receiving preferential treatment.

Inclusion criteria

Patients ≥ 18 years of age with extremity blast- or gunshot-wound(s). ~~covering a confluent area of ≥ 25 cm^2.~~ **In case of multiple wounds the** ~~largest~~ **extremity wound** with the estimated largest area **is selected.**

Exclusion criteria

Wounds presenting >72 hours following initial trauma. Wounds that are considered ready for primary closure by suture or split-thickness skin graft.~~split-thickness skin grafts, i.e. satisfactory granulation already present.~~

Eligible concomitant therapies

Any signs of infection will be treated according to local standard protocols. Wounds in need of debridement will be debrided according to International Committee of the Red Cross (ICRC) war surgery protocols .

Power/Sample size calculation

The sample size calculation was based on detection of a difference of 25% between treatment groups in the proportion of patients for the primary outcome. The expected rate of patients reaching the primary outcome at day five was estimated to be 75% in the NPWT group and 50% in the control group. On the basis of a power of 80% and a significance level of 5%, we calculated that a minimum sample size of 116 patients (58 per group) would be needed to detect a significant difference in the proportions. In order to adjust for dropouts we aim to include 200 patients (100 per group).

Treatments and allocations

Interventions

Patients randomly assigned to NPWT will receive treatment according to manufacturer ~~standardized~~ **treatment guidelines. Patients in the control group will be treated with conventional wound therapy according to local treatment protocols. In both groups dressing changes will be performed according to ICRC war surgery protocols.**

Treatment duration

Until wound closure. Estimated median duration of treatment (control group): five days.

Allocation methods

Block randomization with ~~random~~ two fixed **block sizes will be used to achieve balance in the allocation of participants to the two treatment arms and reduce the opportunity for bias and confounding.**

Degree of blind

Evaluations of wound photographs ~~at day five, fourteen and at follow-up~~ **will be done blinded by two independent, trained evaluators.**

Reason for degree of blinding

Due to the nature of the treatment methods blinding of the patients or staff involved in the treatment would not be possible.

Assessments

Data collection

~~One designated researcher will be responsible for data collection~~Data will be entered into a paper based Case Report Form (CRF) **during the study period. For all patients included in the study contact details including mobile phone number will be** ~~entered into the study protocol~~collected**.** ~~All~~ If possible, **wounds will be photo-documented day 0,** at every dressing~~5~~**,** day **14 and, if possible, at follow-up. Photo documentation will be done in a standardized way with a single coloured background and an adhesive paper ruler attached to the edge of the wound. SRQ-20 scores will be recorded . Aspects of quality of life will be assessed, including noise generated by the NPWT pump, movement impairment, skin irritation, odour,** sleep quality, **discomfort during dressing changes and pain**. For details regarding data collection please see CRF (appendix 6).~~, using Visual Analogue Scale (VAS).~~

Primary endpoint

Wound closure ~~at~~ by **day five, either by suture or split-thickness skin graft.**

Secondary endpoints

- Rate of wound healing, defined as days to ~~delayed~~ wound **closure by suture or split-thickness skin graft**.~~.~~
- **Wound infection,** either verified by positive culture or clinical sign of infection, defined as purulent discharge
- both clinically (exudate) and verified by culture. **Wound size ratio day fourteen (wound size day fourteen divided by size day zero, i.e. wound healing rate after fourteen days)**.~~.~~
- Time until wound is deemed no longer requiring professional care
- Time to discharge
- **Quality of life aspects**.~~.~~
- W~~Full w~~**ound healing at follow-up**.~~.~~
- Septicaemia
- **Mortality**
- ~~.~~**Cost**

Safety outcomes

- Bleeding from wound included in study, leading to blood transfusion
- Sepsis leading to admission to intensive care unit
- Limb amputation (limb with wound included in study)~~.~~

Follow-up procedures

Follow-up will be done at one month and at three months **following the day of wound closure.** Full wound healing or size of wound ~~Presence of wound~~ **at treatment location** ~~or~~

~~not~~ **will be noted. Discharged patients will be contacted by phone. If possible wounds will be photo-documented and evaluated as described above.**

Statistical analyses

Statistical methods

Analysis will be done by intention to treat. A 5% significance level will be used. The difference in dichotomous, such as wound closure at day five, and categorical outcomes with more than two categories between intervention and control group will be tested using chi-square or Fisher test. For differences in continuous outcomes t-test will be used. In order to adjust our analysis by possible confounders and effect modifiers we will then use linear, logistic, ordinal or multinomial regression models, according to the nature of the outcome (continuous, binary, ordinal or nominal) with the outcome as the dependent variable and treatment group as the main explanatory variable. Important demographic and wound specific parameters, such as age, sex, and wound size, will then be included in the model as potential confounders.

Subgroup analyses

Subgroups where NPWT is more/less effective will be identified.

Trial termination criteria

The principal investigator in coordination with the research team will take decision to prematurely terminate the trial if there is evidence of an unacceptable risk for trial subjects (i.e. safety issue) or if there is reason to conclude that it will not be possible to collect the data necessary to reach the study objectives (i.e. insufficient enrolment that cannot be improved). Ethics committees and relevant authorities will be notified of this decision, and the reason for termination.

Wound cultures

A recent review article of infections in conflict wounded emphasizes the importance of differentiating between contaminating and infecting organisms to limit the use of broad-spectrum antibiotics and development of multi-drug resistant organisms . Mapping of bacterial flora and their antibiotic resistance patterns in wounds with clinical signs of infection is crucial in order to establish best treatment strategies. W~~eith the~~ aim ~~of~~ to characterize~~ing~~ the bacterial flora and their antibiotic resistance patterns in wounds originating from the Syrian armed conflict and determine the link between wound infection and morbidity. ~~bacteriological features of clinically infected wounds and determining rate of resistance to antimicrobial agents~~ C~~all c~~ultures **results** and clinical data **for** MSF patients ~~admitted~~ treated at Ar Ramtha hospital and Zaatari refugee camp will be collected from databases and individual charts and analyzed ~~using Stata 12~~. This will include retrospective analysis of routinely collected data within the project since ~~May~~ October 2013~~4~~.

Qualitative component

The healing of a traumatic wound is a complex and dynamic process affected by many different factors, including antimicrobial resistance of bacterial flora and antibiotic use. With the aim of assessing perceptions and attitudes among doctors within the MSF project in Ar Ramtha in relation to wound management, antibiotic use and antibiotic resistance; face-to-face, semi-structured interviews will be conducted. This is a well-

known and widely used research method, previously described for similar studies . Written informed consent will be collected from doctors who agree to participation in the study and aud**io recording of the interviews. Participants will be ensured of confidentiality regarding the content and their identification. The interview transcripts will be analyzed using** manifest and **latent content analysis** ~~.~~

Safety and monitoring

Participant confidentiality

The use of identification numbers will ensure anonymity in the data analysis. The participant's age, gender and demographic characteristics will be used as identifying features for analysis. The research team will ensure the ethical principles of beneficence, non-maleficence, justice, autonomy and respect of patients are adhered to throughout the study.

Data management

All data will remain anonymous throughout the data entry and analysis process. Nominal data will not be distributed outside the study location, or appear in any report or publication. Participant names will only be known by the research team. Identification codes will be safeguarded at MSF facilities for the duration of the study.

Ethical considerations

Ethics

The study will be conducted according to ethical principles stated in the Declaration of Helsinki .

ERB approval

An approval from the Ethics Review Committee of Jordan Ministry of Health will be obtained before initiating the study.

Conflict of interest

This is an investigator ~~research~~ **-initiated study. No company has had any influence over study design. There are no known conflicts of interest with other parties.**

Dissemination

Printed and electronic versions of the final report will be provided to all partners involved in this research, including the Kingdom of Jordan Ministry of Health. Main findings will be presented orally to hospital staff and posted in the Ar Ramtha hospital and Zaatari refugee camp, visible to both staff and patients. The research methodology and results will be presented at scientific conferences and published in peer-reviewed journals.

Appendices

1. Participation information sheet (RCT)
2. Informed consent form (RCT)

3. Participation information sheet (Qualitative component)
4. Informed consent form (Qualitative component)
5. Budget
6. CRF

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Appendix 1: Participation information sheet

This information sheet should remain with the participant (English and Arabic versions)

A prospective, randomized, controlled trial of negative-pressure wound therapy use in conflict-related extremity wounds

Introduction

Médecins Sans Frontières (MSF) and Karolinska Institutet in Sweden, together with **Jordan University of Science and Technology**, is doing research on the best ways to treat extremity wounds **originating from the Syrian armed conflict**. We welcome your participation in this study, but before you decide, it is important for you to know why this research is being done and what it means to be involved. Take your time to decide whether you agree to participate in this study or not.

Background

There is a treatment method called negative-pressure wound therapy (NPWT) that is well established and used in Jordan for the treatment of wounds. The method involves the application of a wound dressing through which a negative pressure is applied. Due to a plastic film overlaying the wound the risk of wound contamination is reduced. NPWT is considered to promote wound healing and prevent infection and has previously been used in the treatment of acute war associated wounds with satisfactory results. We want to compare NPWT with conventional wound dressings in the treatment of extremity wounds and evaluate which **method is more effective.**

Study method

Participants will be put into two groups at random (by chance). In one group participants will be treated with NPWT. In the other group participants will be treated with conventional wound dressings. If you agree to participate you will be treated with either NPWT or conventional wound dressings. Which treatment method you get will be decided randomly (by chance). No matter by which method you will be treated the goal is to heal your wound as quickly as possible.

Potential benefits and risks of participating in the study

NPWT is considered a safe treatment method with the potential benefits of shortened healing time and fewer infectious complications. Potential risks are small bleedings, minor pain and discomfort, mainly associated with dressing changes. Conventional wound dressing has the potential benefits of being a safe treatment method used for many years. Since this method permits air into the wound there is always a potential risk of infection.

Participation

Your participation in this study is voluntary and requires the agreement of you. Once we have started the study, you are free to withdraw without giving any reason. **All data is strictly confidential and** will not be linked to you and your name will not be disclosed. **If published, the results will be presented in a way that no patient can be identified. If you have read and understood all the information on this form and you agree to participate, please sign the consent form attached.**

If you have any questions about the study, please do not hesitate to contact one of the researchers: Dr. Andreas Älgå (mobile: +4670-246 3287, e-mail: andreasalga@yahoo.se) or Dr **Khaldoon Bashaireh** (e-mail: bashaireh@just.edu.jo)

Appendix 2: Informed consent form

English and Arabic versions will be presented to the participant

A prospective, randomized, controlled trial of negative-pressure wound therapy use in conflict-related extremity wounds

[Administer participation information sheet before seeking consent]

I have understood the information contained in the participation information sheet and my questions have been answered to my satisfaction. I give voluntary consent for the participation in this study. I understand that I am free to withdraw from the study at any time **without giving any reason and it will not affect my access to care and treatment.**

Participant name	Mobile phone number	Date	Signature

Research team member name	Date	Signature

~~Participant name~~	~~Date~~	~~Signature~~

~~Research team member~~	~~Date~~	~~Signature~~

Appendix 3: Participation information sheet

This information sheet should remain with the participant

Perceptions in relation to wound management~~, antibiotic resistance and antibiotic use~~: a qualitative study amonghospital-based physicians treatingpatients originating from the Syrian armed conflict

Introduction

Médecins Sans Fronières (MSF) and Karolinska Institutet in Sweden, together with **Jordan University of Science and Technology**, is doing research on the management and healing of war-associated wounds.

We welcome your participation in this study, but before you decide, it is important for you to know why this research is being done and what it means to be involved. Take your time to decide whether you agree to participate in this study or not.

Background

In Ar Ramtha, Jordan MSF is treating patients originating from the Syrian armed conflict. ~~The healing of war-associated wounds is a complex and dynamic process affected by many different factors, including wound management strategies, antibiotic use and antimicrobial resistance.~~

Physicians within the MSF Ar Ramtha project are both Jordanian and international. Specialties range from general physicians to orthopedics and general surgeons. We aim to include 15 doctors of varying origin and specialty. Data will be collected by face-to-face, semi-structured interviews. ~~This is a well-known and widely used research method, previously described for similar studies. Introductory questions will be asked, in relation to the following areas: (i) wound management and antibiotic use in general and (ii) antibiotic resistance within the project in particular.~~ **Estimated time for each interview is 45 minutes. The interviews will be audio recorded. The recordings will be transcribed and the content of the transcripts will be analyzed.**

The aim of the study

The aim of the study is to understand physicians' views on ~~assess attitudes towards antibiotic use and antibiotic resistance and study perceptions about~~ **wound management in the war surgery context.**

Participation

Your participation in this study is voluntary and requires the agreement of you. Participating in this study will not affect your work situation. Once we have started the study, you are free to withdraw without giving any reason. **All data is strictly confidential and** will not be linked to you and your name will not be disclosed. **If published, the results will be presented in a way that no participant can be identified. If you have read and understood all the information on this form and you agree to participate, please sign the consent form attached.**

If you have any questions about the study, please do not hesitate to contact
Dr. Andreas Älgå (mobile: +4670-246 3287, e-mail: andreasalga@yahoo.se)

Appendix 4: Informed consent form

Perceptions in relation to wound management~~, antibiotic resistance and antibiotic use~~: a qualitative study amonghospital-based physicians treatingpatients originating from the Syrian armed conflict

[Administer participation information sheet before seeking consent]

I have understood the information contained in the participation information sheet and my questions have been answered to my satisfaction. I give voluntary consent for the participation in this study. I understand that I am free to withdraw from the study at any time **without giving any reason and it will not affect my work situation.**

Participant name	Date	Signature
Researcher name	Date	Signature

Description	Cost	Quantity	Sum	Sum	Comments
	€		JOD	€	
Human resources					
International staff					
Principal Investigator	0	1		0	Researcher at Karolinska Institutet, Stockholm, Sweden
Case manager	0	1		0	Innovation Unit, MSF-Sweden
National staff					
Research Assistant/Dressing Supervisor	1500	10		150000	50% for the study, 50% for the regular project (salary level 6).
SUB TOTAL				15000	
Material cost					
NPWT pumps	0	5		0	Borrowed (pay for consumables)
NPWT consumables	770,2	60		46209*	Counting 2-3 dressing changes/week and 1-2 canisters/week. Average of 14 days/patient. (*Counting 1 JOD – 1,3 €)
Pad/Lap top	500	1		500	For data collection
Camera	250	1		250	For documentation
Stationary				100	
Printed materials				100	
SUB TOTAL				47159	
Running costs					
Training				300	Excel course, GCP course, photo coarse, other related to study for Research Assistant
Telephone costs	0			100	Covered by project (back up to Skype)
SUB TOTAL				400	
Transports					
International flights	0	4		0	From Sweden to Amman, covered by MSF Sweden IU and KI
Transports within mission				0	Ramtha to Amman, Zaatari, KAUH, etc, covered by project
SUB TOTAL				0	
TOTAL				62 559	

Appendix 5: Budget