Battle Field Casualties
The Royal Netherlands Armed Forces 2006-2010
4 years Uruzgan

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RESEARCH QUESTIONS* Is the currently used RNAF protocol for the acute medical care on the Battlefield sufficient.* What recommendation can be made to enhance this protocol, with emphasis on the transfer of information from battle field to second...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41261

Source
ToetsingOnline

Brief title
Battle Field Casualties

Condition

- Other condition
- Anxiety disorders and symptoms
- Therapeutic procedures and supportive care NEC

Synonym
Battle field casualties, War wounded

Health condition

Militair trauma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: Geen geldstroom eigen kosten

Intervention

Keyword: Armed Forces, Battle Field, Casualties, War

Outcome measures

Primary outcome

Quality of life as assessed by the EuroQol-6D

Secondary outcome

Emotional and health functioning. SF-36

Medical care needs and costs. modified TIC -P

Assessment of Life Habits*shortened version 3.0 (LIFE-H 3.0)

Lower Extremity Functional Scale(LEFS)

Cognitive Emotion Regulation Questionnaire (CERQ)

Symptom checklist (SCL-90)

Impact of Event Scale-Revised (IES-R)

Pain Disability index (PDI)

Screener Traumatic Blast (SKBTB)

Checklist Resilience (CIS)

Study description

Background summary

INTRODUCTION

The Royal Netherlands Armed Forces (RNAF) are currently engaged in a prolonged conflict in Afghanistan. This operation is the largest scale armed conflict for the RNAF since the Second World War.

The experiences of all coalition combat operations in Iraq and Afghanistan have served to highlight the need of innovations and improvement in military medicine and combat casualty care 1. Out-of-hospital treatment of combat casualties is a critical component of emergency medical practice on the battlefield. Accurate understanding of battle injury (BI) is essential to improve tactical combat casualty care (TCCC) 2,3. Earlier studies by several authors have stated the importance of collecting casualty statistics for research programs to improve organisation of healthcare delivery and training of combat medics 4,5. However, prehospital medical documentation of military combat battle injuries and subsequent transferral of this information to the first line hospital is still insufficient or plain deficient.

In his 2009 study, Blackbourne 6 concluded, *There is currently no pre-hospital data for the combat wounded and a system for accurate documentation of pre-hospital care must be found.*

The Joint Theater Trauma Registry (JTTR, JTTS) has greatly enhanced the organization of trauma care in trauma zones, especially with the advent of the joint theater trauma registry. The JTTR, by providing us with snapshots of both injury patterns and outcomes, has helped us to track trends over time. Our challenge now is to complete the registry and add specific injury pattern modules that will allow for detailed epidemiology to direct process improvement, research, and new protective or therapeutic interventions.

An example of a specific injury pattern is the impact of Improvised Explosive Devices (IED) on the lower extremities. Haemorrhage is the major injury mechanism of preventable deaths.

Data on the impact of evacuation time on specific injury patterns will help guide indications for Damage Control Resuscitation (DCR) for medics. In the RNAF no prehospital standardized registration system for the combat wounded exists, therefore we must find a system for standardized documentation of prehospital care. We must also obtain short - and long term follow-up data regarding surveillance of treatment outcomes for the unique mechanisms and wounding patterns of combat, austere surgery, and global evacuation to help us anticipate to unforeseen (long-term) problems after being wounded in combat 7. Therefore we strongly recommend the use of the JTTS or a similar trauma database within the RNAF 8 .

Because the lack of evidence and information concerning protocol, standardized registration and demographics we propose a study. This study evaluates these important questions that need to be answered for optimal initial pre-hospital treatment of Battle casualties, subsequent hospital treatment and long term follow up.

In cooperation with the Ministry of Defence, Leiden University Medical Center (LUMC), Medical Center Haaglanden (MCH) we will conduct this study.

In this study we distinguish the following phases after a battlefield casualty.
* The actual moment of the incident and the direct combat casualty care.
* Transfer of information from the battle field to the second line hospital.
As a warning order to treat the casualty in the role 2 hospital.
* Treatment in the role 2 hospital.
* Possible treatment or rehabilitation in role 3/4 hospital either in Afghanistan or The Netherlands.
* The long term functioning of the Battle Casualties in or outside the RNAF.

In this study the focus will be on the initial Battle Care provided up to the role 2 (1-3) and the long-term follow up (5) of Battle Casualties.

Study objective

RESEARCH QUESTIONS
* Is the currently used RNAF protocol for the acute medical care on the Battlefield sufficient.
* What recommendation can be made to enhance this protocol, with emphasis on the transfer of information from battle field to second line hospital
* What is the long term quality of life of the Battle Casualties.
* What recommendations can be made to enhance the quality of life of soldiers wounded in action on the short and long term.

GOAL
The overall goal of this study is to enhance the standard and quality of care of the battle field casualties of the RNAF.
Of specific interest is the enhancement of the information processes from the initial battle field incident to the second line hospital.
Secondly, given the fact that both (im-)material, emotional and social consequences of battle field casualties is high, now and in the future, this is an area of the highest relevance for the RNAF, the individual soldier and last but not least his/her family.
Results of this study will be submitted to peer reviewed papers, presented at congresses and incorporated in (new) protocols, education and training of all involved professionals.

RATIONALE AND ETHICAL CONSIDERATIONS
This study will recognise and enhance the quality of the short and long term care of persons that perform -national- duties in the RNAF. For the general public it will be an indication of how respectful and professional the (political) leadership in The Netherlands approaches this subject now and more important in the future.
For the persons (patients) involved it may give an extra indication of the importance given to their task to perform (dangerous) missions for their country.

Study design

Phase 1: Crossectioneel Analysis from available data
Phase 2: Observationeel Follow Up, with digital questionnaire (non invasive)
Phase3: Observationeel Follow Up, 10 year analysis

Study burden and risks

Not applicable

Contacts

Public
Medisch Centrum Haaglanden

Lijnbaan 32 Lijnbaan 32
Den Haag 2501CK
NL
Scientific
Medisch Centrum Haaglanden

Lijnbaan 32 Lijnbaan 32
Den Haag 2501CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Battle Field Casualtis

Exclusion criteria

Not battle related

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	19-06-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	22-04-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	06-05-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL38248.058.11