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Predicting multiple organ shutdown after major injury in the emergency setting

Submission date
26/07/2016

Recruitment status
No longer recruiting

Registration date
09/11/2016

Overall study status
Completed

Last Edited
28/01/2019

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Major trauma accounts for a significant number of deaths worldwide, and is one of the most frequent causes of death in people under the age of 40. When a person sustains trauma (injury) to multiple parts of the body (multitrauma) they are at risk of their organs shutting down if their condition is not managed effectively in hospital. Multiple organ dysfunction syndrome (MODS), is a serious condition where two or more organ systems stop working properly. Being able to identify a patient's risk of developing MODS following multitrauma would be very beneficial and help improve the patient's chance of survival. The aim of this study is to find out whether completing a number of standard medical assessments of multitrauma patients can help to predict their chance of developing MODS.

Who can participate?
Adults who have suffered from trauma in multiple body regions.

What does the study involve?
Mutlitrauma patients who have been admitted to the Emergency Department of a participating hospital are assessed by the research team. This involves taking blood samples, physically examining the patients and assessing the extent of their trauma. These assessments are repeated every 24 hours until the patient is discharged from hospital in order to find out if there is a link between the results of these tests and the development of MODS.

What are the possible benefits and risks of participating?
Participants benefit from having the possibility of them developing MODS being identified sooner so they can be treated sooner. There are no notable risks involved with participating.

Where is the study run from?
1. Department of surgery, Univeristy of Sam Ratulangi (Indonesia)
2. Department of surgery, University Diponegoro (Indonesia)
3. Departement of surgery, University Udayana (Indonesia)
4. Departement of surgery, University Hasanuddin (Indonesia)

When is the study starting and how long is it expected to run for?
September 2014 to December 2015

Who is funding the study?
Investigator initiated and funded (Indonesia)

Who is the main contact?
Dr Leo Rendy
dept@rskandou.com

Contact information

Type(s)
Scientific

Contact name
Dr Leo Rendy

ORCID ID
http://orcid.org/0000-0003-2485-6017

Contact details
Sam Ratulangi University
Department of surgery
Gedung bedah swadana
Jl. Raya Tanawangko 56
Malalayang 1
Manado
Indonesia
16161
+662 431 3469191
dept@rskandou.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Multiple organ dysfunction syndrome (MODS) prediction score in multitrauma patients

Study objectives

Injury severity score, revised trauma score, shock, hemoglobin, white blood cells, platelet, and lactate level may predict the occurrence of multiple organ dysfunction syndrome after multitrauma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical board of Kandou hospital, ref: 076/EC-UPKT/VII/2015

Study design
Multi-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Multiple organ dysfunction syndrome

Interventions
New trauma patients admitted to the emergency department of a participating hospital undergo a range of assessments. This involves:
1. Having extra blood samples taken when they undergo blood tests as part of standard care so that the researchers can measure lactate level, blood cell count, and blood gas analysis
2. Undergoing a primary trauma assessment, which involves evaluation of airway, breathing, and circulation (pulse rate, oxygen saturation, blood pressure), disability (mental status whether alert, pain response, verbal response, or no response), and exposure (release clothes and jewelry, exposure of injured area, having been given a blanket to prevent hypothermia).
3. RTS (revised trauma score) and ISS (Injury severity scale) determined, which involves assessing heart rate, respiratory rate, and Glasgow coma scale and an adjuct examination to precisely determine degree of injury in 6 body regions.

Every 24 hours until patients are discharged from hospital, their physical function is assessed through clinical observations (heart rate, urine output, level of consciousness) and further blood samples are taken, looking for signs of MODS development until discharge from hospital.

Intervention Type
Not Specified

Primary outcome measure
Multiple organ dysfunction syndrome (MODS) incidence is measured using sequential organ failure assessment (SOFA) scoring system every day until patients discharged from hospital.

Secondary outcome measures
Mortality is measured during hospitalization and 6 month follow up.

Overall study start date
01/09/2014

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Age between 16 and 65 years old
2. Multitrauma patients (trauma in multiple body regions)
3. Injury severity score (ISS) ≥16
4. No chronic illness as comorbidities, no previous major trauma with or without surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Minor trauma
2. Previous major trauma

Date of first enrolment
01/11/2014

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
Indonesia

Study participating centre
Department of surgery, Univeristy of Sam Ratulangi
Jl. Raya Tanawangko
Gedung Bedah swadana RSUP Kandou
Manado
Indonesia
95115

Study participating centre
Department of surgery, University Diponegoro
Fakultas Kedokteran Universitas Diponegoro (UNDIP)
Jl. Dr. Soetomo 18
Jawa Tengah
Indonesia
50271

Study participating centre
Departement of surgery, University Udayana
Jl. Kesehatan no.1
Denpasar
Bali
Indonesia
80114

Study participating centre
Departement of surgery, University Hasanuddin
Jl. Perintis Kemerdekaan KM. 10
Tamalanrea Indah
Makassar
Kota Makassar
Sulawesi Selatan
Indonesia
90245

Sponsor information

Organisation
Sam Ratulangi University

Sponsor details

Kandou General Hospital
Departement of Surgery
Jl. raya tanawangko
Manado
Indonesia
95115
+624313469191
mail@rskandou.com

Sponsor type
University/education

Website
http://faked.unsrat.ac.id/psilbedah

ROR
https://ror.org/01cn6ph21

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in high impact trauma or surgery journals

Intention to publish date
01/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017	28/01/2019	Yes	No