

Predicting multiple organ shutdown after major injury in the emergency setting

Submission date 26/07/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/01/2019	Condition category Signs and Symptoms	<input type="checkbox"/> 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?

Multitrauma 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
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Contact information

Type(s)
Scientific

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Additional identifiers

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

Primary study design

Observational

Study design

Multi-centre cohort study

Study type(s)

Screening

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 adjunct 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(s)

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

Key secondary outcome(s)

Mortality is measured during hospitalization and 6 month follow up.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

<https://ror.org/01cn6ph21>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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