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Lung complications after traumatic pelvic fracture in intensive care patients

Submission date
27/09/2015

Recruitment status
No longer recruiting

Registration date
28/10/2015

Overall study status
Completed

Last Edited
21/04/2016

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
The pelvis is a butterfly-shaped fused ring of bones which sit at the bottom of the spine. Fractures of the pelvis are most commonly caused by serious injuries (major trauma), such as in a car accident or fall from a great height. When a person sustains major physical trauma, direct or indirect complications often arise. Acute respiratory distress syndrome (ARDS) is a life-threatening condition, where the lungs are unable to provide the body with adequate oxygen to meet its' requirements. This condition is one of the most common lung complications when a person is already critically ill or seriously injured. The aim of this study is to find out how common lung complications such as ARDS are in people who have a traumatic pelvic fracture.

Who can participate?
Adults admitted to an intensive care unit (ICU) at Uppsala University Hospital with a fractured pelvis between 2007 and 2014.

What does the study involve?
Records of patients are accessed from the publically available pelvic fracture database. The researchers then record the amount of these patients who suffered any lung complications during their stay in intensive care.

What are the possible benefits and risks of participating?
There are no potential benefits or risks of participating in this study.

Where is the study run from?
Department of Anesthesiology and Intensive Care Medicine, Uppsala Academic Hospital (Sweden)

When is the study starting and how long is it expected to run for?
February 2013 to January 2016

Who is funding the study?
Uppsala County Council (Sweden)

Who is the main contact?
Mr Joakim Engström

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pulmonary complications after pelvic fracture in critically ill patients

Study objectives
The aim of the study is to investigate the hypothesis with the primary end-point of lung complication rate in all patients that has been admitted to an ICU at Uppsala University Hospital between 2007 and 2014 due to pelvic fracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board, Uppsala (Regionala etikprövningsnämnden, Uppsala), 09/08 /2006, ref: 2006/140

Study design
Single-centre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Lung complications after traumatic pelvic fracture

Interventions
From the pelvic fracture database, data from patient who have been admitted to one of the ICUs at Uppsala University Hospital between 2007 and 2014 is collected. Data that will be extracted is: date of injury, type of pelvic fracture, SAPS3, EMR, comorbidity, other injurys, origin of trauma, ISS, AIS, time to surgery, blood loss during surgery, ICU stay in days, ventilatory support, time in ventilatory support, p/F-ratio, pulmonary radiology, complication rate, vasoactive drugs, duration of need of vasoactive drugs, laboratory data, morbidity and mortality.

Intervention Type
Other

Primary outcome measure
Acute respiratory distress syndrome (ARDS) frequency will be recorded from information in the pelvic fracture database during the intensive care period after the injury occurs.

Secondary outcome measures
Frequency of other lung complications (pneumonia, pneumothorax and pulmonary embolism) will be recorded from information in the pelvic fracture database during the intensive care period after the injury occurs.

Overall study start date
01/02/2013

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Patients admitted to any of the ICUs at Uppsala University Hospital after traumatic pelvic fracture between 2007-2014

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100-200 patients

Key exclusion criteria
1. Patients without an informed consent
2. Pregnancy
3. Patients not admitted to an ICU during hospital stay

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala Academic Hospital
Department of Anesthesiology and Intensive Care Medicine
ANIVA Ing70, 1 tr
Uppsala
Sweden
75185

Sponsor information

Organisation
Uppsala County Council (Sweden)

Sponsor details
Slottsgränd 2
Uppsala
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753 09

Sponsor type
Government

Website
www.lul.se

ROR
https://ror.org/01dv86r63

Funder(s)

Funder type
Government

Funder Name
Uppsala County Council

Results and Publications

Publication and dissemination plan
Plan to publish the study results in a major trauma journal.

Intention to publish date
01/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/04/2016		Yes	No