Lung complications after traumatic pelvic fracture in intensive care patients

Submission date 27/09/2015	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 28/10/2015	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 21/04/2016	Condition category Respiratory	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 lifethreatening 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 Mr Joakim Engström

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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

 Aged 18 or over
 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 Sweden 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?
<u>Results article</u>	results	19/04/2016		Yes	No