Nonoperative versus operative treatment for flail chest and multiple rib fractures after blunt thoracic trauma. A multicenter prospective cohort study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23596

Source
Nationaal Trial Register

Brief title
OPVENT2

Health condition

rib fracture; blunt thoracic trauma; nonoperative; rib fracture fixation; hospital length of stay; intensive care unit length of stay

Sponsors and support

Primary sponsor: DePuy Synthes
Source(s) of monetary or material Support: DePuy Synthes

Intervention

Outcome measures

Primary outcome

- Intensive care unit length of stay for patients with a flail chest

- Hospital length of stay for patients with multiple rib fractures

Secondary outcome

- Numerical rating scale (NRS) for pain on day 3, 5, 7 and 14

- Pneumonia during hospital stay; date of pneumonia

- In hospital mortality

- Days of epidural / IV / systematic analgesia (morphine)

- Number of days admitted to Intensive Care Unit (ICU)

- Number of days on mechanical ventilation`

- Number of days in need oxygen therapy

- Vital capacity

- Tracheostomy yes / no

- Number of complications during admission

- Total number of days admitted in the hospital

- Quality of life as measured with EQ5D-5L 1 year after trauma

- Lung function related problems as measured with the mMRC 1 year after trauma

- Implant related complaints and removal yes / no

- Cost-effectiveness of rib fixation

- Chest tube yes/no

Study description

Background summary

Patients with thoracic injury and multiple rib fractures are at high risk of serious health outcomes. Nonoperative treatment for flail chest and multiple rib fractures has been the gold standard but there is an increasing popularity for rib fracture fixation in the last two decades, however, the literature remains scarce. The aim of this large multicentre prospective cohort study is to compare rib fixation with nonoperative treatment for flail chest or multiple rib fractures by evaluating treatment effects in ‘real-world’ patients treated in different level 1 trauma centers by means of a propensity score matched analysis.

Study objective

The aim of this large multicentre prospective cohort study is to compare rib fixation with nonoperative treatment of a flail chest and multiple rib fractures by evaluating treatment effects in ‘real-world’ patients treated in different level 1 trauma centers.

Study design

- hospital admission

- 6 weeks after discharge

- 1 year after discharge

Intervention

Rib fracture fixation for patients with a flail chest or multiple rib fractures

Contacts

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Eligibility criteria

Inclusion criteria

All adult (over 18 years) patients presenting at the Emergency Department (ED) of the participating hospitals with a CT scan confirmed flail chest or multiple rib fractures after blunt thoracic trauma will be enrolled in the cohort.

Exclusion criteria

- Mentally impaired patients who are unable to fill in the EQ5D-5L questionnaire

- Non-traumatic rib fractures

- Rib fractures as a result of cardiopulmonary resuscitation

- Allergy for titanium

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	250
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-11-2017
Application type:	First submission

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
NTR-new	NL6647
NTR-old	NTR6833
Other	METC : 17-544/C

Study results