The value of bronchodilators and anti-inflammatory medication in patients with posttraumatic rib fractures, a multicenter prospective cohort study (RIB-Inhalation)

No registrations found.

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

Summary

ID

NL-OMON25831

Source
Nationaal Trial Register

Brief title
RIB-Inhalation

Health condition

Multiple rib fractures

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Pneumonia during primary hospital admission

Secondary outcome

- Pulmonary function (forced vital capacity and forced expiratory volume in 1 second),
- Occurrence of thoracic complications
- Occurrence of symptoms indicative of side effects of bronchodilators
- Hospital length of stay

Study description

Background summary

Rationale: Rib fractures are common in patients who sustained blunt chest trauma. One of the main goals of treatment is to prevent the patients from developing pneumonia. Changes in treatment focused on enabling the patient to breath easily and to clear mucus effectively. Bronchodilation might, in theory, be helpful in reaching this goal, however no data are available in posttraumatic patients. Various side-effects of bronchodilators have been reported, e.g., innocent but annoying for the patients are a dry mouth and nausea, seen in 1-10% of the users. More dangerous are reported side-effects like arrhythmia, elevated systolic blood pressure, and tremor, reported in 0.1-1% of the patients.
Objective: The primary aim is to determine the effect of bronchodilators during primary hospital admission on the occurrence of pneumonia in patients with multiple (≥3) rib fractures. Secondary aims are to determine in these patients the effect of bronchodilators on the pulmonary function measured using spirometry, the level of thoracic pain in rest and during maximum inspiration, the occurrence of thoracic complications, the occurrence of symptoms indicative of side effects of bronchodilators, and the hospital length of stay (HLOS) of primary hospital admission.
Study design: Multicenter, prospective, cohort study.
Study population: Patients aged 16 or older, admitted for multiple (≥3) rib fractures (CT-confirmed) after blunt chest trauma, with a Glasgow coma scale (GCS) score or 15.
Intervention: Use of bronchodilators versus no use of bronchodilators
Outcome measures: The primary outcome measure is the occurrence of pneumonia during primary hospital admission. Secondary outcome measures are pulmonary function (forced vital capacity and forced expiratory volume in 1 second), the occurrence of thoracic complications, the occurrence of symptoms indicative of side effects of bronchodilators, and hospital length of stay.

Study objective

The use of bronchodilators reduces the risk of pneumonia during primary hospital admission

Study design

Daily during hospital admission, and at 30 days after trauma

Intervention

- Daily multiple times use of bronchodilators during primary hospital admission
- No use of bronchodilators during primary hospital admission

Contacts

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Eligibility criteria

Inclusion criteria

1) Age 16 years or older
2) Hospital admission with ≥3 rib fractures (CT-confirmed) after blunt chest trauma
3) Chest CT-scan within 24h after trauma
4) GCS score 15
5) Provision of informed consent by patient

Exclusion criteria

1) Use of bronchodilators in the last week before trauma
2) Known pregnancy
3) Previous thoracic surgery (e.g., lung resection)
4) Previous pulmonary problems, requiring continuous oxygen at home pre-trauma

5) Congenital thoracic deformity (e.g., pectus excavatum, pectus carinatum, severe scoliosis, or kyphosis)
6) Planned transfer to other hospital during primary admission
7) Insufficient comprehension of the Dutch language to understand the study documents in the judgement of the treating physician or research team

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
Undecided

Ethics review

Positive opinion

Date:	03-07-2021
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	NL9588
Other	METC Erasmus MC : MEC-2021-0502

Study results

Summary results
None yet