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

Gepubliceerd: 03-07-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25831

Bron
Nationaal Trial Register

Verkorte titel
RIB-Inhalation

Aandoening

Multiple rib fractures

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pneumonia during primary hospital admission

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Daily during hospital admission, and at 30 days after trauma

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Undecided

Ethische beoordeling

Positief advies

Datum:	03-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9588
Ander register	METC Erasmus MC : MEC-2021-0502

Resultaten

Samenvatting resultaten
None yet