Comparing Restrictive vs. Liberal Oxygen Strategies for Trauma Patients: The TRAUMOX2 Trial

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53478

Source
ToetsingOnline

Brief title
TRAUMOX2

Condition

- Other condition
- Injuries NEC

Synonym
Injury, Trauma

Health condition

lichamelijk trauma na ongeval

Research involving
Human

Sponsors and support

Primary sponsor: Rigshospitalet Kopenhaben
Source(s) of monetary or material Support: Novo Nordisk Foundation (betaling Erasmus MC vanuit Rigshospitalet Kopenhagen)

Intervention

Keyword: Oxygen, Resuscitation, Trauma

Outcome measures

Primary outcome

The primary outcome measure will be a combined endpoint of 30-day mortality and/or major respiratory complications (pneumonia and ARDS) within 30 days.

Secondary outcome

The secondary outcome measures will be mortality at 30 days and 12 months after trauma, major respiratory complications (pneumonia and ARDS) within 30 days, hospital length of stay (HLOS), Intensive Care Unit length of stay (ICU LOS) and days alive outside the ICU, time on mechanical ventilation (until 30 days), days alive without mechanical ventilation and number of re-intubations within 30 days, pneumonia post-discharge within 30 days, episodes of hypoxaemia during intervention (saturation <90%), surgical site infections within 30 days, EQ-5D-5L score at 6 months and 12 months post-trauma, and GOSE score at 6 months and 12 months post-trauma.

Study description

Background summary

In the trauma population, oxygen administration is often standard of care.
However, the evidence supporting oxygen administration in this population is

extremely limited. In a recent pilot study (TRAUMOX1), we found evidence that maintenance of normoxaemia following trauma is feasible. Furthermore, we found that the incidence of mortality and lung complications tended to be higher amongst hyperoxemic patients.
In TRAUMOX2, we hypothesize that a restrictive compared to a liberal oxygen strategy for the initial eight hours after trauma will result in a lower rate of 30-day mortality and/or major respiratory complications (pneumonia and ARDS) within 30 days (combined endpoint).

Study objective

The main aim is to compare the effect of a restrictive versus liberal oxygen strategy the first eight hours after trauma on the incidence of 30-day mortality and/or major respiratory complications (pneumonia and ARDS) within 30 days (combined endpoint).

Study design

An international, multicentre, parallel-grouped, superiority, outcome assessor- and analyst-blinded, randomised, controlled, clinical trial with regards to treatment: treating staff will be aware of the randomisation group.

Intervention

Restrictive (intervention) versus liberal (control) oxygen treatment.

Study burden and risks

In the restrictive oxygen group, the risk of hypoxia is avoided as all trial participants are monitored closely during the eight hours intervention with continuous pulse-oximetry and arterial blood gases to avoid desaturations. Liberal oxygen treatment is similar to the current guidelines, and thus there will be no additional risk compared to trial participants not enrolled in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Patients aged >=18 years, including fertile women*
2) Blunt or penetrating trauma mechanism
3) Direct transfer from the scene of accident to one of the participating trauma centres
4) Trauma team activation (basic or extended trauma team)
5) The enrolling physician must initially expect a hospital length of stay for 24 hours or longer
6) Deferred consent by patient or proxy

Exclusion criteria

1) Patients in cardiac arrest before or on admission
2) Patients with a suspicion of carbon monoxide intoxication
3) Patients with no/minor injuries after secondary survey will be excluded if they are expected to be discharged <24 hours
4) Insufficient comprehension of Dutch language (also applies to person providing proxy consent)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-05-2022
Enrollment:	275
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Conoxia, 100% medicinal gas, compressed or liquid
Generic name:	Oxygen
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-12-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-02-2022
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
Other	Clinicaltrials.gov Registration number: NCT03491644
EudraCT	EUCTR2021-000556-19-NL
CCMO	NL79921.078.21