Pharmacodynamics of pancuronium during therapeutic hypothermia.

No registrations found.

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

Summary

ID

NL-OMON23344

Source
NTR

Brief title
PANCOOL

Health condition

cardiac arrest, therapeutic hypothermia, neuromuscular blockade, train-of-four, pancuroniumbromide

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Median during untill TOF ratio 0.9 after 24 hours of pancuroniumbromide infusion.

Secondary outcome

N/A

Study description

Background summary

After cardiopulmonary resuscitation (CPR) is a nowadays common to treat survivors with therapeutic hypothermia for 24-48h. A lot of intensive care units use pancuroniumbromide as muscle relaxants during this therapeutic hypothermia. From normothermic patients we know there is a large interindividual variance in duration of action. After CPR and during hypothermia even more factors can be associated with a prolonged action of pancuroniumbromide. Therefore we want to conduct this observational trial, to measure the duration of action of pancuroniumbromide when given for 24h during therapeutic hypothermia after CPR.

Study objective

How long is the (median) duration from discontinuation of pancuronium after approximately 24h infusion until neuromuscular recovery to a TOF 0.9 in patients treated with therapeutic hypothermia after cardiac arrest?

Study design

Time of injection pancuronium (time 0);

Injection pancuronium – TOF ratio 0.7;

Injection pancuronium – TOF ratio 0.9;

Injection pancuronium – TOF ratio 1.0;

TOF ratio at planned discontinuation of sedation.

Intervention

Pancuroniumbromide infusion during 24 hours.

Contacts

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Eligibility criteria

Inclusion criteria

Patient criteria:

1. Age > 18 years.

Cooling criteria:

1. Witnessed cardiac arrest;

2. Initial cardiac rhythm being VF/VT;

3. Delay from arrest till start CPR >5min, <15min;

4. Time from arrest till return of spontaneous circulation (ROSC) <60min;

5. Start cooling within 6 hours after ROSC.

Exclusion criteria

Exclusion from cooling (MUMC based):

1. Cardiac shock >30min after ROSC;

2. Coma before cardiac arrest;

3. Other cause of coma (CVA, trauma, intoxication);

4. Hypothermia on arrival at emergency department (<30 degrees Celsius);

5. Verbal reaction after ROSC;

6. Pregnancy;

7. Persistent hypoxia (SpO2<85%) >15min after ROSC;

8. Terminal disease state;

9. Pre-existing coagulation disorders (trombolysis is no contra-indication);

10. Persistent ventricular arrhythmias.

Exclusion because of study criteria:

1. Age < 18 years;

2. Contraindications for use of pancuronium;

3. No option for neuromuscular monitoring on at least one hand;

4. Use of confounding medication (anticonvulsants, steroid therapy, verapamil or aminoglycosides);

5. Renal failure;

6. Liver failure;

7. Neuromuscular diseases;

8. Use of other neuromuscular relaxants than pancuronium.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2011
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-10-2011
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	NL2968
NTR-old	NTR3115
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A