

Comparison of intranasal and intramuscular naloxone in opioid overdoses managed by ambulance staff: a double dummy, randomised, controlled trial

Arne Skulberg, MD, Ph. D.

Consultant anaesthetist, Oslo University Hospital Air Ambulance Department

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Conflict of interest


NTNU has licence agreement with Farmaholding AS to commercialise a naloxone nasal spray, Ventizolve 1.26 mg naloxone

NTNU has full ownership of all data in this trial, and Farmaholding AS or others have not been part of analysis or interpretation of results

Prof Ola Dale may earn royalties from any sale of nasal spray through NTNU/ TTO

I have no benefit, financial or in-kind from the sale of any naloxone product

Comparison of intranasal and intramuscular naloxone in opioid overdoses managed by ambulance staff: a double-dummy, randomised, controlled trial

Arne Kristian Skulberg^{1,2,3}  | Ida Tylleskär^{1,4}  | Morten Valberg⁵ | Anne-Cathrine Braarud² | Jostein Dale^{3,4} | Fridtjof Heyerdahl^{2,3} | Tore Skålhegg² | Jan Barstein⁴ | Sindre Mellesmo² | Ola Dale¹ 

Design

Hypothesis:

Intranasal naloxone is not inferior to intramuscular

Primary endpoint:

Restoration of spontaneous respiration within 10 minutes

Inclusion criteria:

Suspected opioid overdose

unconscious

reduced breathing

miosis

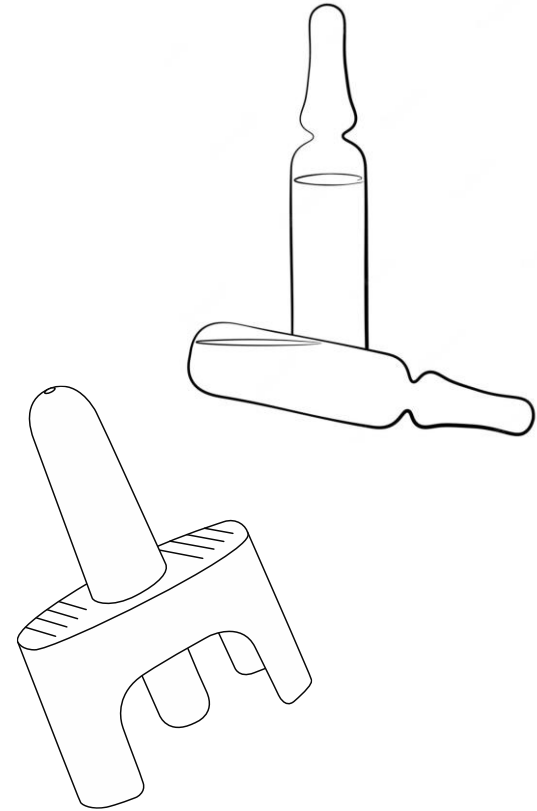


Drugs compared

Intramuscular 0.8 mg / 2ml naloxone

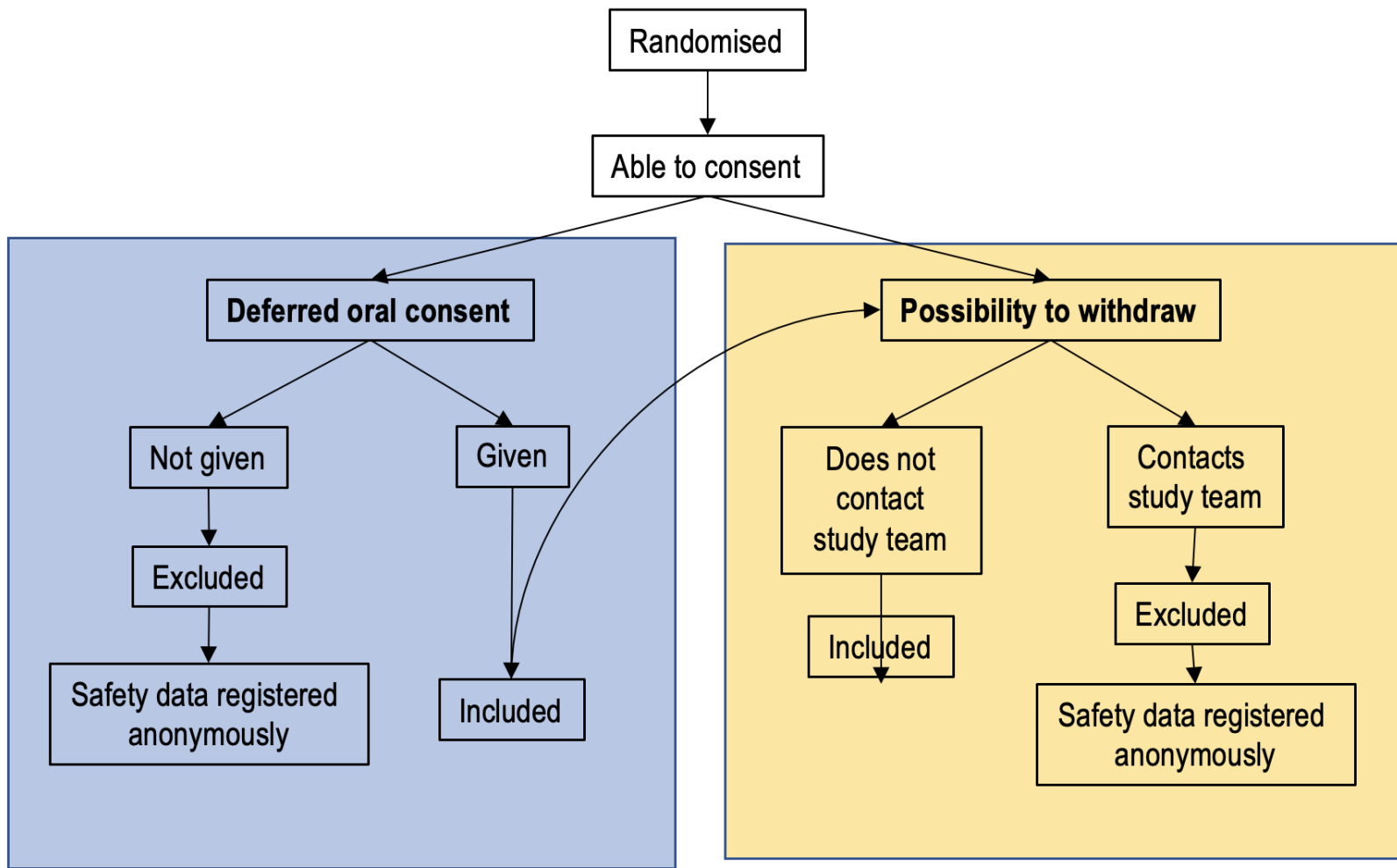
vs

intranasal 1.4 mg/0.1 ml naloxone



Double dummy design allows blinding





Baseline at inclusion

		Overall %
Respiratory rate (breaths per minute)	0	28
	1-4	41
	5-8	31
Glasgow Coma Score	3/15	78
	4-11/15	22

Results

How many achieved spontaneous breathing within 10 min after one dose of the study drug?

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Intramuscular group: 105 of 108 participants (97.2%)

Intranasal 74 of 98 participants (79.6%)

Adverse Events

	Treatment Group	
	Intramuscular n= 129	Intranasal n=109
Bradycardia		1
Nausea	5	7
Vomiting		2
Drug withdrawal syndrome	15	5
Dizziness	1	
Headache	5	4

Conclusion

Intramuscular naloxone 0.8 mg had almost 100% effect- too high for titration

Intranasal naloxone 1.4 mg/ dose 80% effect end well tolerated

Thank you

Ola Dale

Ida Tylleskar

Ambulance workers in Oslo and Trondheim

Co- authors

Oslo University Hospital

NTNU

St. Olav's Hospital

