

Efficacy and safety of targeting lower arterial oxygen saturations to reduce oxygen toxicity and oxidative stress in very preterm infants: the Canadian Oxygen Trial

Submission date 22/08/2006	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 22/08/2006	Overall study status Completed	☐ Protocol
Last Edited 08/05/2013	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00637169

Protocol serial number

Study information

Scientific Title

Acronym

COT

Study objectives

In infants who are born at gestational ages of 23^{0/7} to 27^{6/7} weeks, does lowering the concentration of supplemental oxygen to target an arterial oxygen saturation by pulse oximetry (SpO₂) of 85-89% compared with 91-95%, from the day of birth until the baby's first discharge home, increase the probability of survival without severe neurosensory disability to a corrected age of 18 months?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Board, McMaster University (Hamilton Health Sciences) approved on August 10, 2006; REBs for other four countries are pending.

Study design

Two arm randomised parallel controlled trial with study participant, investigator, caregiver, outcome assessor, and data analyst blinded.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory insufficiency of prematurity

Interventions

Exerimental arm: supplemental oxygen to maintain functional arterial oxygen saturations in the range of 85-89%. Dose of oxygen is determined by the individual infant's need to achieve the target oxygen saturations.

Duration: Until first discharge to home.

Control arm: Supplemental oxygen to maintain functional arterial oxygen saturations in the range of 91-95%. Dose of oxygen is determined by the individual infant's need to achieve the target oxygen saturations.

Duration: Until first discharge to home.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Survival without severe neurosensory disability to 18 to 21 months (corrected for prematurity)

Key secondary outcome(s))

1. Retinopathy of prematurity measured at 32 to 44 weeks postmenstrual age
2. Bronchopulmonary dysplasia measured at 36 weeks postmenstrual age
3. Brain injury, measured from the week one of life up to 36 weeks postmenstrual age
4. Patent ductus arteriosus, measured until first discharge to home
5. Necrotising enterocolitis measured until first discharge to home
6. Growth, measured until a corrected age of 18 to 21 months
7. Respiratory morbidity, measured until a corrected age of 18 to 21 months
8. Mean developmental index scores on the Bayley Scales measured at the corrected age of 18 to 21 months

Completion date

28/02/2011

Eligibility**Key inclusion criteria**

1. Gestational age 23^{0/7} to 27^{6/7} weeks
2. Postnatal age less than 24 hours, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Infant not considered viable
2. Dysmorphic features or congenital malformations that adversely affect life expectancy or neurodevelopment
3. Known or strongly suspected cyanotic heart disease
4. Persistent pulmonary hypertension
5. Unlikely to be available for long-term follow-up

Date of first enrolment

01/10/2006

Date of final enrolment

28/02/2011

Locations

Countries of recruitment

Argentina

Canada

Finland

Germany

Norway

Study participating centre

McMaster University

Ontario

Canada

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Sponsor information

Organisation

McMaster University (Canada)

ROR

<https://ror.org/02fa3aq29>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-79217)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/05/2013		Yes	No