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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

Registration date
22/08/2006

Last Edited
08/05/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00637169

Secondary identifying numbers
MCT-79217

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/10/2006

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

Age group
Neonate

Sex
Both

Target number of participants
1200

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
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Sponsor information

Organisation
McMaster University (Canada)

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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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