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A study about the use of whole body cooling for severe respiratory distress due to meconium aspiration syndrome (MAS) in neonates

Submission date
21/11/2015

Recruitment status
No longer recruiting

Registration date
24/11/2015

Overall study status
Completed

Last Edited
04/11/2016

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hypoxic-ischemic encephalopathy (HIE) is a brain injury caused by lack of oxygen. Cooling (called whole body hypothermia [WBH]) is the standard treatment for newborn babies affected by HIE occurring at delivery. HIE is often associated with meconium aspiration syndrome (MAS), a severe respiratory problem that often occurs in newborns together with HIE. MAS occurs when a newborn baby breathes a mixture of meconium and amniotic fluid into the lungs around the time of delivery. The aim of this study is to clarify the effect of WBH on oxygenation and respiratory outcomes in MAS.

Who can participate?
Newborn babies with MAS born during 2006-2014 who were treated or not treated with WBH for HIE .

What does the study involve?
The clinical outcomes of babies who were treated with WBH are compared with the clinical outcomes of babies who were not treated with WBH.

What are the possible benefits and risks of participating?
There are neither benefits nor risks for participants.

Where is the study run from?
Eleven neonatal or pediatric intensive care units in Europe, Australia, South and North America. The study is being coordinated at the South Paris University Hospitals (France).

When is the study starting and how long is it expected to run for?
January 2006 to November 2015

Who is funding the study?
Not provided at time of registration

Who is the main contact?
Prof. Daniele De Luca

Contact information

Type(s)
Scientific

Contact name
Prof Daniele De Luca

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Whole body hypothermia and meconium aspiration syndrome: international multicentre retrospective cohort study

Acronym
MASH (Meconium Aspiration Syndrome Hypothermia)

Study objectives
Whole body hypothermia might improve gas exchange and clinical outcomes in MAS patients, especially in those with more severe lung disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the French Society for Critical Care (SRLF), 19/11/2015, ref: 15/08

Study design
International multicentre retrospective cohort study (observational)

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Meconium aspiration syndrome

Interventions
The intervention being tested is whole body hypothermia. There are interesting animal and translational data suggesting the usefulness of whole body hypothermia for some forms of respiratory failure although this has never been studied on clinical grounds before. Conversely, hypothermia is already an established therapy for hypoxic ischemic encephalopathy (HIE).

The study cohort consisted of babies affected by MAS and treated with whole body hypothermia (WBH) according to TOBY trial criteria for HIE ('cooled' neonates). The control cohort consisted of MAS babies with or without a diagnosis of HIE, in whom TOBY criteria were not met and WBH was not started ('uncooled' neonates) .

Intervention Type
Procedure/Surgery

Primary outcome measure
Gas exchange over the first 72 hours of life (as described by oxygenation index, PaCO2 and pH)

Secondary outcome measures
1. Duration of invasive mechanical ventilation
2. Total duration of respiratory support (defined as the total time spent under invasive, non-invasive ventilation, continuous positive airway pressure/high flow nasal cannulae and free oxygen therapy)
3. Length of stay in the intensive care unit
4. Length of hospital stay

Overall study start date
01/01/2006

Completion date

01/11/2015

Eligibility

Key inclusion criteria
Study cohort consisted of MAS neonates treated with WBH according to the TOBY trial criteria (see above).
Control cohort consisted of MAS babies in whom TOBY criteria were not met and WBH was not instigated.

All babies had to fulfill the following MAS diagnostic criteria:
1. Meconium-stained amniotic fluid
2. Need for intubation and tracheal suctioning in the delivery room according to the American Academy of Pediatrics neonatal resuscitation guidelines
3. Typical chest radiograph appearance
4. Oxygenation index (OI) > 10 at the intensive care unit admission

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Pilot study (impossible to calculate given the lack of preliminary data on the topic)

Key exclusion criteria
1. Major congenital malformation or known chromosomal abnormalities
2. Any lung disease other than MAS
3. Need for extra-corporeal membrane oxygenation (ECMO)

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Australia

Brazil

England

France

Italy

Netherlands

Spain

United Kingdom

United States of America

Study participating centre
South Paris University Hospitals
Medical Center "A. Beclere"
Division of Pediatrics and Neonatal Critical Care
France
92140

Study participating centre
Università Cattolica del Sacro Cuore
Policlinico Universitario "A. Gemelli"
TIN e TIP
Italy
00168

Study participating centre
Murdoch Childrens Research Institute
Neonatology
Royal Children’s Hospital
Department of Paediatrics
University of Melbourne
Australia
VIC 3052

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1105 AZ

Study participating centre

NICU Hospital "La Paz"
Universidad Autonoma de Madrid
Spain
28029

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals NHS Trust
United Kingdom
OX39DU

Study participating centre
University Hospital of University of São Paulo
Department of Pediatrics
Brazil
2565

Study participating centre
San Francisco General Hospital
UCSF University of California
United States of America
CA 94110

Study participating centre
Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico
Department of Clinical Sciences and Community Health
Università degli Studi di Milano
Italy
20122

Study participating centre
Women’s and Children Hospital "G. Salesi"
Polytechnical University of Marche
Italy
60123

Study participating centre

University of Sheffield
United Kingdom
S10 2TN

Sponsor information

Organisation
Individual sponsor (Italy)

Sponsor details
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Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Study results have been or will be (at least partially) presented at the main European meetings (ESPNIC 2015 and ESPR/jENS 2015) and at the Pediatric Academic Societies Meeting in the US (PAS/SPR 2015). During 2015/2016 a full paper should be sent for publication in a major international journal.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016		Yes	No