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Safety and efficacy of topiramate in neonates with hypoxic ischemic encephalopathy treated with hypothermia (NeoNATI)

Submission date 26/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/06/2011	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Neonatal Diseases	

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
2010-018627-25

IRAS number

ClinicalTrials.gov number

NCT01241019

Secondary identifying numbers
2010-018627-25

Study information

Scientific Title
Safety and efficacy of topiramate in neonates with hypoxic ischemic encephalopathy treated with hypothermia: a pilot study of the Neonatal Neuroprotection of Asphyxiated Tuscan Infants (NeoNATI) Network

Acronym
NeoNATI

Study objectives
To determine whether the administration of topiramate to newborns with hypoxic-ischemic encephalopathy (HIE) potentiates the neuroprotective effect of treatment with hypothermia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Azienda Ospedaliero-Universitaria "A. Meyer" of Florence; approved on January 10, 2010

Study design
Two-centre interventional pilot randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Hypoxic Ischemic Encephalopathy (HIE)

Interventions

Newborns with moderate to severe hypoxic ischaemic encephalopathy at two centres in Florence and Pisa will be randomised to one of the following treatment arms:
1. Intervention group: Newborns with hypoxic ischemic encephalopathy treated with therapeutic hypothermia wiil receive topiramate (TPM) 10 mg/kg once a day, administered with an orogastric tube as enteric-coated granules mixed with water on arrival in the NICU, when the cooling will be begun (T0), once a day for the first 3 days of life, for a total of 3 doses per patient.
2. Control group: Newborns with hypoxic ischemic encephalopathy will be treated only with mild hypothermia

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Topiramate

Primary outcome measure
1. Survival rate
2. General movements at 7-10 days and after 12 weeks of life
3. Neurological examination including:
3.1. Gross motor function at 7-10 days, 12 weeks, 6 months, 12 months, 18 months of life using Dubowitz neurological examination and Bayley test
3.2. Acoustic functions at 7-10 days, 6 months, 12 months and 18 months of life
3.3. Visual functions at 7-10 days, 6 months, 12 months and 18 months of life

Secondary outcome measures
Efficacy of treatment with topiramate for improving neuroradiological outcome at 3 and 12 months of life using cerebral Magnetic Resonance Imaging (MRI) (standard, with diffusion tensor imaging and with Spectroscopy)

Overall study start date
09/02/2010

Completion date
01/02/2012

Eligibility

Key inclusion criteria
1. Newborns with gestational age > 36 weeks and birth weigh > 1800 g with at least 1 of the following:
1.1. Apgar score < 5 at 10 minutes
1.2. Persisting need for resuscitation, including endotracheal intubation or mask ventilation 10 minutes after birth
1.3. Acidosis (pH <7.0, base deficit >-16 mmol/L in umbilical cord blood or arterial, venous or capillary blood) within 60 minutes from birth
2. Moderate to severe encephalopathy, consisting of altered state of consciousness (irritability,

lethargy, stupor, or coma) and > 1 of the following signs:
2.1. Hypotonia
2.2. Abnormal reflexes, including oculomotor or pupil abnormalities
2.3. Absent or weak suck
2.4. Clinical seizures
3. Abnormal ambulatory electroencephalogram (aEEG)

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
60 participants from two centres in Florence and Pisa

Key exclusion criteria
1. Congenital abnormalities
2. Congenital viral infections
3. Evidence of encephalopathy other than HIE

Date of first enrolment
09/02/2010

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
Italy

Study participating centre
A. Meyer University Childrens Hospital
Florence
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I-50139

Sponsor information

Organisation
A. Meyer University Childrens Hospital (Italy)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01n2xwm51

Funder(s)

Funder type
Government

Funder Name
General Directorate for Health Law and Policy of Solidarity, Area Coordinating Health, Division of Research, Development and Labor Protection in the Region of Tuscany (Italy) - Regional Health Research Program 2009

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?
Protocol article	protocol	05/09/2012		Yes	No
Results article	results	01/04/2018	16/01/2019	Yes	No