ISRCTN77393684 https://doi.org/10.1186/ISRCTN77393684

The HyP-HIT Study

Submission date
06/03/2007

Recruitment status
No longer recruiting

Registration date
06/03/2007

Overall study status
Completed

Last Edited
28/10/2010

Condition category
Nervous System Diseases

[_] 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

Protocol serial number
MCT-50398

Study information

Scientific Title
Hypothermia Paediatric Head Injury Trial

Acronym

HyP-HIT

Study objectives
Hypothermia therapy will improve long term (neurological, functional and cognitive) outcomes following traumatic brain injury in children.

Please note that this trial was submitted for an ISRCTN in September 2005 but was not assigned at the time due to incomplete data.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Research Ethics Committee of Children's Hospital of Eastern Ontario on the 26th October 1998.

Primary study design
Interventional

Study design
Multicentre, international, randomised, two arm, therapeutic management strategy trial, with outcome assessor and data-analyst blinding.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Paediatric traumatic brain injury

Interventions
Group one: Hypothermia therapy, oesophageal temperature (32 - 33°C)
Group two: Normothermia, oesophageal temperature (36.5 - 37.5°C)
Duration: 24 hours

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Paediatric Cerebral Performance Category (PCPC) score, six months post head injury.

Key secondary outcome(s)
1. The proportion of children achieving independent function, measured at one, three and 12 months post-head injury
2. Paediatric Injury Functional Outcome Score (IFOS), King's outcome score for childhood head injury, Glasgow Outcome Scale (GOS), GOS-expanded for children and adolescents, measured at one, three and 12 months post-head injury
3. Intelligence quotient, memory, speed of processing and attention, distractibility and behavioural rating scores, measured at three and 12 months post-head injury

4. Measures of cerebral physiology, complication rates and lengths of intensive care unit and hospital stay, during acute hospital stay

Completion date
31/10/2005

Eligibility

Key inclusion criteria
1. Informed consent by a parent or legal guardian
2. Aged one year up to and including 17 years, either sex, with diagnosis of traumatic brain injury
3. Have a Glasgow Coma Score less than or equal to eight (severe traumatic brain injury according to the recent guidelines assessed at the tertiary level paediatric hospital
4. With a Computed Tomography (CT) scan showing intra-cranial haemorrhage, diffuse axonal injury or cerebral oedema
5. Who are mechanically ventilated

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 Years

Upper age limit
17 Years

Sex
All

Key exclusion criteria
1. Who are in refractory shock defined as a hypotension despite intravenous colloid and red cell transfusions exceeding 80 cc/kg
2. With a suspected diagnosis of clinical brain death as defined as fixed and dilated pupils, Glasgow Coma Scale of three and no evidence of brain function on neurological examination
3. Who remain pulseless after arrival in the emergency department despite advanced cardiac life support including at least one dose of epinephrine
4. With high cervical (C1 to C5) cord injury
5. With a severe neurodevelopmental disability (Paediatric Cerebral Performance Category scores (see primary outcome) prior to head injury
6. Who have head injury secondary to a penetrating injury (e.g. gunshot wound)
7. Who have an acute epidural haematoma and are expected to recover rapidly following surgical evacuation of the haematoma
8. Who are randomised (and initiation of cooling for patients randomised to hypothermia) more than eight hours following the estimated time of injury

9. Who are pregnant (diagnosed by serum Human Chorionic Gonadotropin [HCG])
10. Whose parents/legal guardian refuse consent

Date of first enrolment
01/10/1998

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
United Kingdom

Canada

France

Study participating centre
Department of Critical Care Medicine
Ontario
Canada
M5G 1X8

Sponsor information

Organisation
Childrens Hospital of Eastern Ontario Research Institute (CHEORI) (Canada)

ROR
https://ror.org/05nsbhw27

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca/ (ref: MCT-50398)

Funder Name
Childrens Hospital of Eastern Ontario Research Institute (CHEORI) (Canada)

Funder Name
Ontario Neurotrauma Foundation (Canada)

Alternative Name(s)
Fondation ontarienne de neurotraumatologie, ONF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Funder Name
Hospital for Sick Children Foundation (Canada)

Funder Name
Physicians Services Inc. (Canada)

Funder Name
Québec Health Research Fund (Fonds de la recherche en santé du Québec [FRSQ]) (Canada)

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	05/06/2008		Yes	No