

The HyP-HIT Study

Submission date 06/03/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/03/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design

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

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/1998

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

Age group

Child

Lower age limit

1 Years

Upper age limit

17 Years

Sex

Both

Target number of participants

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**

Canada

France

United Kingdom

Study participating centre

Department of Critical Care Medicine

Ontario

Canada

M5G 1X8

Sponsor information**Organisation**

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

Sponsor details

401 Smyth Road
Ottawa
Ontario
Canada
K1H 8L1
+1 613 737 7600 ext 2686
brazeau@cheo.on.ca

Sponsor type

Hospital/treatment centre

Website

<http://www.cheori.org/>

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

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	05/06/2008		Yes	No