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Immediate cooling of the brain during the resuscitation period by the use of a pharyngeal cooling device

Submission date	Recruitment status	[_] Prospectively registered
23/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/08/2019	Surgery	

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

Secondary identifying numbers

UMIN000002224

Study information

Scientific Title
Immediate cooling of the brain during the resuscitation period by the use of a pharyngeal cooling device: a randomised controlled trial

Acronym
i-Cool

Study objectives
This study was designed to elucidate the effects of pharyngeal cooling initiated during or immediately after resuscitation on tympanic temperature, neurological recovery and mortality rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Okayama University Ethics Committee approved on the 4th February 2009 (ref: 620)

Study design
Randomised controlled trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Brain hypothermia

Interventions
Methods used for resuscitation will comply with AHA Guidelines (2005).

Treatment group:
Immediately after tracheal intubation, the pharyngeal cooling cuff will be inserted and pharyngeal cooling will be initiated. Otherwise, the treatment procedures conventionally

performed at the medical facility will be conducted. Required procedures of pharyngeal cooling:
1. Rate of perfusion: 500 mL/min
2. Perfusion pressure: 50 - 20 cm H2O
3. Perfusate: Physiological saline (5°C)
4. Target tympanic membrane temperature: 32°C
5. Cooling duration: 2 hours
Conditions for ending treatment:
1. When spontaneous circulation does not return and resuscitation measures have been discontinued
2. When pharyngeal cooling has been performed for greater than 2 hours

Control group:
Treatment conventionally performed at the medical facility will be conducted.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Lowest tympanic membrane temperature within 2 hours of start of pharyngeal cooling
2. Time until tympanic temperature decreases by 1.0°C

Secondary outcome measures
1. Functional prognosis:
1.1. Evaluation of level of consciousness: Glasgow Coma Scale 2 weeks after resuscitation
1.2. Evaluation of neurological function: Glasgow Pittsburgh Cerebral Performance categories evaluated 1 and 6 months after resuscitation
2. Life prognosis:
2.1. Return of spontaneous circulation (ROSC); ROSC defined as a return of palpable pulse: ROSC time, rate of ROSC
2.2. Mortality rate: Mortality rates at 1, 3, and 6 months after resuscitation
3. Incidence rate of complications during 3-day period after start of resuscitation: acute lung injury, systemic inflammatory response syndrome, sepsis, dialysis, pericutaneous cardiopulmonary support, thrombocytopenia, coagulopathy, arrhythmia
4. Subgroup analysis: Evaluation of effect of cooling, functional prognosis, and life prognosis, based on as-treated analysis in compliance with the protocol, such as pharyngeal cooling time
5. Subgroup analysis: Evaluation of functional prognosis and life prognosis of subgroups of patients surviving 6 hours and 24 hours
6. Subgroup analysis: Effect of cooling, and evaluation of functional prognosis and life prognosis, in subgroup of patients who did not undergo pericutaneous cardiopulmonary support or intravenous administration of cold fluids
7. Subgroup analysis: Duration of stay in intensive care and duration of hospital stay, in subgroup of patients who survived

Overall study start date
01/06/2009

Completion date
31/03/2010

Eligibility

Key inclusion criteria
1. Patients with witnessed cardiogenic cardiac arrest or witnessed non-cardiogenic cardiac arrest except post-traumatic cardiac arrest
2. Patients who have been resuscitated by medical services within 15 minutes after the onset of cardiac arrest
3. Aged 16 - 89 years old, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Total final enrolment
108

Key exclusion criteria
1. Patients with a disorder in the pharynx or oesophagus
2. Patients with severe hypothermia (less than 34 degrees centigrade upon arrival)
3. Patients who are pregnant
4. Patients with an immunodeficiency or medicated with an immunosuppressant (except for steroids)
5. Patients with brain damage initiated by a mechanism other than cardiac arrest
6. Rejection by a person in parental authority
7. Barthel Index Score of less than 66

Date of first enrolment
01/06/2009

Date of final enrolment
31/03/2010

Locations

Countries of recruitment
Japan

Study participating centre
Okayama University Hospital
Okayama

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Sponsor information

Organisation
Okayama University (Japan)

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Sponsor type
University/education

Website
http://www.cc.okayama-u.ac.jp/~cool/index.html

ROR
https://ror.org/02pc6pc55

Funder(s)

Funder type
Government

Funder Name
Ministry of Health, Labor and Welfare (Japan) (ref: H19- Trans- General-005)

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	01/12/2014	21/08/2019	Yes	No