Name of reviewer:

Notes:

Study ID: (First author and initials, title of (primary) report, year)

Report ID: (study ID; First author and initials, title of secondary report, year)

Study population (tick all that apply)
TBI

Stroke

Cardiac arrest

neonatal HIE

Other - specify

Study in adults (≥18 years):
Yes

No

Mixed

Unclear

Study outcomes:

Randomized:
Yes

No

Unclear

Methods (quality checklist from Cochrane Renal Group)

Study design
(RCT – parallel group, crossover; observation – cohort, case-control; descriptive e.g. safety, feasibility, case report)

Total study duration

Selection bias
Sequence generation (randomised trial)
Random: Yes/No/Unclear

Method:

Allocation sequence concealment

A. Adequate - randomisation method described that would not allow investigator or participant to know or influence intervention group before eligible participant entered in the study.
B. Unclear - Randomisation stated but no information on method used is available.
C. Inadequate - Method of randomisation used such as alternate medical record numbers or unsealed envelopes; any information in the study that indicated that investigators or participants could influence the intervention group.

Control for confounders (cohort study)
Yes/No/Unclear

Matching (case-control study)
Yes/No/Unclear

Performance and detection bias
Blinding (randomised trials and cohort studies)

Blinding of investigators: Yes/No/not stated
Blinding of participants: Yes/No/not stated
Blinding of outcome assessor: Yes/No/not stated
Blinding of data analysis: Yes/No/not stated

The above are not considered blinded if the treatment group can be identified in > 20% of participants because of the side effects of treatment.

Measurement of exposure (cohort and case-control studies) – differences between groups that could affect outcome of interest e.g. in measurement of outcome of interest (was measurement unbiased)

Case definition (case-control studies)

Attrition bias
Intention to treat

Yes - specifically reported by the authors that intention-to-treat analysis was undertaken and this was confirmed on study assessment.
Yes - not stated, but confirmed on study assessment.
No - not reported and lack of intention-to-treat analysis confirmed on study assessment. (Patients who were randomised were not included in the analysis because they did not receive the study intervention, they withdrew from the study, or were not included because of protocol violation).
No - stated but not confirmed upon study assessment.
Not stated.

Completeness of follow-up (cohort, case-control studies)
Yes
No
Unclear

Other concerns about bias
e.g. if not blinded, systematic differences in care other than intervention

Participants

Total number

Setting

Mechanism of injury/diagnostic criteria

Age

Gender

Cooling interventions
Under intervention details give cooling methods, devices, pharmacological cooling. Possible cooling interventions include:

non-invasive head cooling – cooling applied externally to head (+/-neck), nasal and/or pharyngeal cooling;
no cooling intervention or standard care;
physical cooling interventions applied systemically or to parts of the body other than the head e.g. tepid sponging, ice packs, cooling blankets and mattresses, intravascular cooling catheters;
pharmacological cooling interventions e.g. paracetamol, non-steroidal anti-inflammatory drugs, cyclo-oxygenase inhibitors, ethymisole.

Total number of intervention groups e.g. cooled groups, control groups:

For each intervention group

1. Intervention

Intervention details (sufficient for replication, if feasible)

Target temperature

Duration of intervention

Number allocated to group

Rewarming strategy
Controlled

Passive

Rate of rewarming (state °C/°F)

2. Intervention

Intervention details (sufficient for replication, if feasible)

Target temperature

Duration of intervention

Number allocated to group

Rewarming strategy
Controlled

Passive

Rate of rewarming (state °C/°F)

3. Intervention

Intervention details (sufficient for replication, if feasible)

Target temperature

Duration of intervention

Number allocated to group

Rewarming strategy
Controlled

Passive

Rate of rewarming (state °C/°F)

Barbiturates used:
No
Yes - give details:

Outcomes and Results

1. **Intracranial temperature** (state °C/°F)
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean(SD) or 2x2 table)

Estimate of effect with confidence interval & p value

2. **Core trunk temperature** (state °C/°F) – PA, oesophagus, bladder or rectum
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean(SD) or 2x2 table)

Estimate of effect with confidence interval & p value

3. **Mortality**
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean(SD) or 2x2 table)

Estimate of effect with confidence interval & p value

4. **Disability/dependency (include method of assessment e.g. GOS)**
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

5. **Reduction in intracranial pressure**
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

6. **Improvement in biochemical markers of injury e.g. lactate/pyruvate ratio, glutamate, cytokines**
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

7. **Improvement in cross-sectional imaging**
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

8. **Complications and adverse effects actually or possibly attributable to the head cooling intervention or the specific device**, e.g. infections, prolonged clotting time and bleeding complications, scalp damage
Collected:
No
Yes

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

9. **Time from brain injury or onset of stroke to start of cooling (not HIE)**
Collected:
No
Yes

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

10. **Cooling rate (e.g. hourly temperature reduction)** (not HIE)
Collected:
No
Yes

Time point(s) collected at:

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

11. **Time from injury to target temperature (not HIE)**
Collected:
No
Yes

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

12. **Time from device application to achieving target temperature (not HIE)**

Collected:
No
Yes

Reported:
No
Yes

Sample size

Missing participants (% of pts excluded or lost to follow-up)

Summary data for each intervention group (e.g. mean (SD) or 2x2 table)

Estimate of effect with confidence interval & p value

Miscellaneous

Funding source

Declared conflicts of interest

Key conclusions of study authors

Miscellaneous comments from study authors

References to other relevant studies

Correspondence required

Miscellaneous comments by reviewers