**Data Extraction Form**

***(The form should be adapted in order to follow the published review protocol)***

**Review title:**

**Review author:**

**Date:**

**Article URL:**

|  |  |  |
| --- | --- | --- |
| First author | Journal/Conference Proceedings | Study and Year |
|  |  |  |

Contact Address:

Source of Sponsorship:

**Study eligibility**

|  |  |  |  |
| --- | --- | --- | --- |
| RCT | Relevant participants | Relevant interventions | Relevant outcomes |
| Yes / No / Unclear | Yes / No / Unclear | Yes / No / Unclear | Yes / No\* / Unclear |

\* The issue relates to selective reporting – when authors may have taken measurements for particular outcomes, but have not reported these within the paper(s). Review authors should contact trial authors for information on possible non-reported outcomes & reasons for exclusion from publication. The study should be listed in ‘Studies awaiting assessment’ until clarified. If no clarification is received after three attempts, the study should then be excluded.

|  |
| --- |
| Do not proceed if any of the above answers are ‘No’. If the study is to be included in ‘Excluded studies’ section of the review, the record below the information should be inserted into ‘Table of excluded studies’. |
|  |

**References to trial**

Check other references identified in searches. If there are further references to this trial, link the papers now and list below. All references to a trial should be linked under one Study ID in RevMan.

|  |  |  |  |
| --- | --- | --- | --- |
| Code each paper | Author(s) | Journal/Conference Proceedings etc | Year |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Participants and trial characteristics

|  |  |
| --- | --- |
| **Participant characteristics** | |
|  | Further details |
| Age (mean, median, range, etc) |  |
| Sex of participants (numbers/%, etc) |  |
| Disease status/type, etc (if applicable) |  |
| Other |  |

Trial characteristics

Study design: Ο Parallel group Ο Cross-over Ο Open label

Comments:

Intervention: Ο Treatment Ο Other

Treatment comparator: Ο Placebo Ο Other:

Fill in the table for each intervention (i.e. paracetamol alone, ibuprofen alone, combined paracetamol and ibuprofen, alternating paracetamol and ibuprofen, other)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intervention |  |  |  |  |
| Dose  Max dose |  |  |  |  |
| Method of administration |  |  |  |  |
| Frequency of administration |  |  |  |  |
| Time-points when measurements were taken during the study |  |  |  |  |
| Time points reported in the study |  |  |  |  |
| Method of temperature measurement: ie. Rectal, oral, etc |  |  |  |  |

\* include timepoints for temperature measurement

Risk of bias

|  |  |
| --- | --- |
| **Sequence generation** | |
| Method: | Grade (circle) |
|  | Yes (Random) |
| No (e.g. alternate) |
| Unclear |

|  |  |
| --- | --- |
| **Concealment of allocation**  **Process used to prevent foreknowledge of group assignment in a RCT, which should be seen as distinct from blinding** | |
| Method: | Grade (circle) |
|  | Yes |
| No |
| Unclear |

|  |  |  |
| --- | --- | --- |
| **Blinding** | | |
| Person responsible for participants care | Yes / No / Unclear | |
| Participant | Yes / No / Unclear | |
| Outcome assessor | Yes / No / Unclear | |
| Other (please specify) | Yes / No / Unclear | |
| **Incomplete outcome data:** Incomplete outcome data addressed? | | |
| No missing outcome data? | Yes / No / Unclear | |
| Reasons for missing data unlikely to be related to true outcome | Yes / No / Unclear | |
| Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups | Yes / No / Unclear | |
| For dichotomus data: proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on intervention effect estimate | Yes / No / Unclear | |
| For continuous data, plausible effect size among missing outcomes not enough to have clinically relevant impact on observed effect size | Yes / No / Unclear | |
| Missing data have been imputed using appropriate methods | Yes / No / Unclear | |
| **Selective outcome reporting** | | |
| Study protocol available and all pre-specified outcomes of interest in the review have been reported in the pre-specified way | Yes / No / Unclear | |
| Study protocol is not available but is clear that published reports include all expect outcomes, including those that were pre-specified | Yes / No / Unclear | |
| **Other potential threats to validity** | | |
| Study appears to be free of other sources of bias | | Yes / No / Unclear |
| Describe potential sources of bias: ie. Potential bias source related to study design, extreme baseline imbalance, stopped early due to data-dependent process, claimed to have been fraudulent, etc | |  |

# Were withdrawals described? Yes No not clear

# Discuss if appropriate…………………………………………………………………………………………

…………………………………………………………………………………………………………

**Data extraction**

|  |
| --- |
| **Primary outcomes** |
|  |
|  |
|  |
|  |
| **Secondary outcomes** |
|  |
|  |
|  |
|  |
|  |

**Results**

Adverse Events: Described Yes No

If Yes Patient Specific Overall Statistic

**Adverse events:**

Number of adverse events (fill in specific interventions, ie. Ibuprofen alone,paracetamol alone, combined)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type | Intervention 1 | Intervention 2 |  |  |
| GI |  |  |  |  |
| Skin |  |  |  |  |
| Others |  |  |  |  |
| Total |  |  |  |  |

Comments:

**Withdrawals due to adverse events: (see Table 1 appendix)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Intervention 1 | Intervention 2 |  |  |
| Number of withdrawals |  |  |  |  |

**Outcomes for Patient Subgroups: specify subgroups**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **For Continuous data (ie. Timepoints for blood pressure) add columns as necessary** | | | | | | |
|  | Unit of measurement  Degrees C | Intervention 1 | | Intervention 2 | | Details if outcome only described in text | |
| N | Mean (SD) | n | Mean (SD) |  | |
|  |  |  |  |  |  |  | |
|  |  |  |  |  |  |  | |
|  |  |  |  |  |  |  | |

|  |  |  |
| --- | --- | --- |
| **For Dichotomous data (ie. pain vs no pain) add columns as necessary** | | |
| **Outcome (fill in)** | **Intervention 1**  **n = number of participants, not number of events** | **Intervention 2**  **n = number of participants, not number of events** |
|  |  |  |
|  |  |  |
|  |  |  |

**Other outcomes: (ie. Patient comfort scales)**

|  |
| --- |
| **Other information which you feel is relevant to the results**  Indicate if: any data were obtained from the primary author; if results were estimated from graphs etc; or calculated by you using a formula (this should be stated and the formula given). In general if results not reported in paper(s) are obtained this should be made clear here to be cited in review. |
|  |

|  |  |  |
| --- | --- | --- |
| References to other trials  **Did this report include any references to** published reports **of potentially eligible trials not already identified for this review? No** | | |
| **First author** | **Journal/Conference** | **Year of publication** |
|  |  |  |
| **Did this report include any references to** unpublished data **from potentially eligible trials not already identified for this review? No If yes, give list contact name and details** | | |
|  | | |

Appendix 1

|  |  |
| --- | --- |
| **Trial characteristics** | |
|  | Further details |
| Single centre / multicentre |  |
| Country / Countries |  |
| How was participant eligibility defined? |  |
| How many people were randomised? |  |
| Number of participants in each intervention group |  |
| Number of participants who received intended treatment |  |
| Number of participants who were analysed |  |
| Median (range) length of follow-up reported in this paper (state weeks, months or years or if not stated) |  |
| Time-points you are using in Meta-View |  |
| Trial design (e.g. parallel / cross-over\*) |  |
| Other |  |

\* If cross-over design, please refer to the Cochrane Editorial Office for further advice on how to analyse these data