Corticosteroids as co-analgesics with opioids for cancer related pain: A feasibility study

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None

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4
510
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Steroids are essential for maintaining homeostasis and regulating a wide variety of physiological processes in the human body. Therapeutically they are used for the treatment of inflammation, auto-immune disorders and malignancies. Corticosteroids are commonly used in management of cancer pain however there is limited quality data supporting their efficacy for this purpose (1,2). A recent Cochrane systematic review in 2015 evaluated the efficacy of corticosteroids in treating cancer-related pain in adults (3). In this review there were fifteen studies that met the inclusion criteria, with a total of 1926 participants enrolled. There was great variation in the type and route of corticosteroids used in the included studies. The conclusion of this review was that the evidence of the efficacy of corticosteroids for pain control in cancer patients is weak. Given the widespread use of corticosteroids in advanced cancer and concerns around efficacy and adverse effects, further trials are needed to evaluate the safety and effectiveness of steroids.

In order to add to the data currently available for the Cochrane meta-analysis, the aim of this randomised, double-blind, placebo controlled study was to assess the feasibility to proceed to a RCT study assessing the analgesic benefit of parenteral dexamethasone when used in conjunction with opioids for the treatment of cancer related pain. A sample size of 20 was considered adequate to test the primary feasibility end-point.

The primary outcome was the percentage of randomised patients who progressed to complete the study. Participants had to have uncontrolled pain secondary to cancer and/or its treatment with a Brief Pain Inventory average pain score of ≥3 despite optimised treatment with opioids and appropriate co-analgesics. Optimised opioid therapy was reached once clinically inappropriate to increase the dose due to opioid related side-effects, or where no further efficacy benefit was expected. Patients were excluded if they had concurrent corticosteroids or use within 7 days of study at doses equivalent to or greater than study doses. The medication solutions were either dexamethasone 8mg in 2mls or placebo (2mls of normal saline), administered either subcutaneously or intravenously.
A total of 140 patients were screened. Only one patient was able to be enrolled and complete the study. The main reasons for exclusion are outlined in Table 1.

This study showed that it was not feasible to recruit patients to a trial of parenteral dexamethasone as a co-analgesic in patients with cancer related pain within the confines of these inclusion criteria. This study highlighted various important factors which excluded patients from participation in the study, particularly the large percentage of patients already using steroids. It also highlighted the need to undertake feasibility studies to test the appropriateness of the methodology of planned studies, therefore providing the opportunity to alter the recruitment approaches based on the experience whilst screening patients. In the absence of evidence to the contrary, the ongoing clinical approach to the use of corticosteroids for cancer-related pain should be to use the lowest effective dose, for the shortest possible time with close monitoring for adverse effects (4).
References


Table 1: Reasons for failure to recruit

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Ineligible patients (n=139)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>% (n)</td>
</tr>
<tr>
<td>Already on steroids</td>
<td>44% (62)</td>
</tr>
<tr>
<td>Unstable analgesia</td>
<td>25% (35)</td>
</tr>
<tr>
<td>Cognitive impairment/ dementia/ delirium</td>
<td>8% (11)</td>
</tr>
<tr>
<td>Currently/ planned radiotherapy</td>
<td>6% (8)</td>
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<tr>
<td>End-of-life / deteriorating / fluctuating GCS</td>
<td>5% (7)</td>
</tr>
<tr>
<td>Minor factors (bowel obstruction, bacteremia, non-English speaking background, on drug trial)</td>
<td>11% (16)</td>
</tr>
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