Riluzole: a new agent for amyotrophic lateral sclerosis
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Authors' objectives
To comprehensively review the efficacy of riluzole in the treatment of amyotrophic lateral sclerosis (ALS).

Searching
MEDLINE was searched in May 1996. Manufacturer's information was used when there was no primary literature.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were included.

Specific interventions included in the review
Riluzole (2-amin-6-(trifluoromethoxy)-benzothiazole).

Participants included in the review
Patients with amyotrophic lateral sclerosis (ALS) (commonly known as Lou Gehrig's disease) were included.

Outcomes assessed in the review
For efficacy, the primary outcomes mentioned in the trials include time to tracheostomy, death and functional status (measured on a 4 point scale incorporating scores for limb function, bulbar function, patient symptom reports, and clinical examination). Secondary outcomes include muscle strength, respiratory function, Clinical Global Impression of Change scale scores, patient's evaluation of symptoms, and visual analogue scales assessing fasciculations, tiredness, stiffness and cramping.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
A detailed critical evaluation of each study is included. The authors do not state how the papers were assessed for validity, or how many of the authors performed the validity assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
A narrative review was undertaken

How were differences between studies investigated?
Differences between the studies were investigated in a narrative discussion

Results of the review
Two trials (2,073 participants) were included.
In the included trials, riluzole extended the time to tracheostomy or death, and the effect was greatest with dosages of 100 mg/d or more. No effect on patients' symptoms or global assessment was detected at 18 or 21 months. However, several flaws in these trials have led to questions concerning the validity of these results. Adverse effects were noted, the most common being transient elevation of liver enzyme concentrations (2-5 times the upper limit of normal), worsening of asthenia, nausea, vomiting, diarrhoea, anorexia, dizziness, vertigo, somnolence and mouth paresthesia. Neutropenia occurred in 3 out of 4000 patients.

Cost information
A 30-day supply of riluzole (60 tablets containing 50 mg) has an average wholesale price of $727.75 (US dollars).

Authors' conclusions
Although the benefits of riluzole are questionable and it is expensive, this agent may extend the time to tracheostomy or death in patients with ALS. At present, this is the only agent approved for the treatment of ALS and should be made available for these patients.

CRD commentary
The summary mentions only 2 large scale trials, and it is unclear whether there are other smaller trials which have not been included in the review. Also, the search is limited and searches of other databases (e.g. EMBASE) would have uncovered other relevant studies. There are few methodological details relating to the review itself. It is therefore unclear whether the results of the review are robust. As there are only 2 large trials included, the conclusions of the review may be susceptible to publication bias.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.