

## Gene therapy for cleft lip and palate.

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Extensive studies have established a mutual association between genetic predominance and environmental factors, leading to cleft lip and palate (CLP). Currently, CLP is being treated using a multidisciplinary approach.

Gene therapy has a promising future and is under development for the treatment of various diseases. What about CLP? Recently a statement denying the near future possibility of achieving a cure through somatic cell gene therapy (SCGT) was made.<sup>1</sup> However, there is extensive research going on currently, regarding the identification of new alleles associated with CLP mutations.

Even if the provision of cure through SCGT is possible, what is the benefit of genome wide association studies to the patient or clinician? Due to the unknown risks involved with therapy many organizations have already discontinued experimentation.<sup>1</sup> What are the moral and ethical considerations that need to be considered for trials of gene therapy for the treatment of CLP, once all the associated genes are verified?

Extensive scoring of genes for risk factors might not be clinically significant, especially in such a complex disease in which large gene-environment interactions play a role.<sup>2</sup> In addition, ethnic and geographic variations have also been documented which makes gene therapy difficult to achieve soon. Benefits of gene therapy must outweigh the current therapeutic approach and the potential risks of the new therapy, for its implementation and assessment.<sup>3-4</sup> If through a miracle we develop a gene-based therapy, will it have wide availability and cost-effectively planned provision?<sup>5</sup>

There is a high tendency to indulge in extensive studies to identify and document genes related to a certain disease without focusing on the clinical implications. Gene therapy can provide a new platform for diagnosis and prevention of such complex diseases at embryonic stages. Nevertheless, ample stress towards clinical assessment of therapies is vital to develop applicable therapeutic strategies.

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