ORAL PRESENTATION





Modelling cost-effectiveness and value of information in clinical trials to inform stop go decisions: results from the arctic study

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Background

Trial interim analyses are traditionally based on an assessment of efficacy and safety. Early evaluation of cost-effectiveness and a quantification of the societal value of further research could provide additional information to inform stop-go decisions.

Objective

To assess the potential utility of early cost-effectiveness analysis (CEA) and value of information analysis (VOIA) within the context of a randomised clinical trial.

Methods

The ARCTIC trial randomised patients with previously untreated Chronic Lymphocytic Leukaemia to receive fludarabine, cyclophosphamide, mitoxantrone and low dose rituximab (FCM-miniR) or fludarabine, cyclophosphamide and rituximab (FCR; standard care). An interim efficacy analysis was conducted after 103 patients had completed therapy. CEA and VOIA were conducted using a Markov decision model, based on subsequent data from 200 patients.

Results

The trial was terminated early based on the results of the interim efficacy analysis. FCM-MiniR was not expected to be cost-effective over a lifetime horizon, producing an average lifetime cost saving of £7,708 and health loss of -0.67 QALYs. The VOIA, however, suggested a high value of further research due to uncertainty around key parameters. Whilst the CEA results support the interim efficacy findings, the VOIA results highlight the cost of

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trial termination in terms of potential population net health loss (1,050 QALYs) by foregoing the opportunity to collect additional data.

Conclusion

Early evaluation of cost-effectiveness within clinical trials could provide useful information in addition to efficacy data for interim analyses. Future research proposals should incorporate CEA and VOIA at interim analysis, allowing research-value to influence stop-go decisions.

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