FINAL REPORT

Introduction

Oral mucositis is an inflammatory and frequently ulcerative side effect of cancer therapy, which has been identified by patients as the most debilitating side effect of their treatment. Mucositis is a dose limiting toxicity which exerts a substantial clinical and economic impact and negatively affects patient quality of life. The patient experience of mucositis is under-reported in the literature. To date, no interventions have been identified that have proven successful in the prevention of mucositis for patients receiving all types of therapy. Vitamin E has shown conflicting results in clinical trials. This project uses lessons learned from previous studies together with the results of a feasibility study to identify a best practice model for future trials.

Methods

A feasibility study was designed, developed and conducted which investigated vitamin E for the prevention of mucositis in patients undergoing conditioning for bone marrow transplantation. Through lessons learned from previous studies, consultations with medical professional, the MHRA, ethics committee and suppliers, a protocol was developed for a double blind RCT. The process of gaining MHRA and ethical approval, and the repackaging of intervention and placebo products to meet MA-IMP requirements are key Aspects of the project.

Results

Although only nine patients were recruited into the feasibility study, a number of issues affecting the design and conduct of future trials were identified. Recruitment in particular was identified to be problematic. Strategies for overcoming this problem in future trials were identified. The methods of blinding and allocation concealment employed were found to be feasible for use in future trials. Expected adverse events patients undergoing stem cell transplantation were also reported and were minimal. No obvious differences in the trial outcome were observed in descriptive analysis, but no statistical tests were applied due to the small number of patients and the underpowered sample.

We have stopped the trial when the vitamin E preparations came to their used by date.

Continuation of this trial with very low recruitment and need to re-apply for MHRA approval and all other statutory approvals, within the timelines of a PhD student project, was not feasible.

Conclusion

Further studies are required to investigate interventions for the prevention of mucositis. It is of upmost importance that these trials are rigorous in both their methodology and subsequent reporting in order to elicit the maximum benefit for patients taking part in clinical trials, and future patients undergoing therapy for cancer.

Dissemination:

No dissemination of these findings is planned, due to the underpowered sample. Patients have received a summary of the findings.