ABSTRACT

Outcome Objectives:

Codeline is no longer recommended for children under the age of 12 due to the risk of respiratory depression. This is a protocol for a randomised controlled trial to determine whether GeloRevoice™ throat lozenges are effective as adjunct therapy for standard analgesia in post tonsillectomy pain.

Methods:

72 patients will be randomized to two groups. Parents with children aged 6-18 undergoing tonsillectomy will be asked to consent to the study. The intervention group will receive GeloRevoice™ throat lozenges and the control group will receive a placebo. The study will be subject to local ethical approval.

Results:

The primary endpoint is a visual analogue pain scale for paediatric populations. Pain scores will be recorded on a diary card daily for two weeks post operatively. Diary card data will be collected via a telephone interview at the end of two weeks. Visual analogue scale data will be compared between two groups using a two-tailed t-test where p<0.05 is considered to be statistically significant.

METHODS AND MATERIALS

A total of 72 patients will be randomized to two groups. We calculated power using a two sided test with standard deviation assumed to be 1.5 and alpha set at 0.05. A sample size of 36 per group is required to achieve power of 80%. Parents with children aged 6-18 undergoing tonsillectomy will be approached to participate in the study. After consent is obtained, the patients will be allocated to two groups with computer generated random numbers. The intervention group will receive GeloRevoice™ throat lozenges and the control group will receive a placebo in plain packaging and asked to use as required alongside analgesia prescribed according to a standard regimen in our hospital for post tonsillectomy pain. Both the patients and the investigators will be blinded to group allocation.

TRIAL PROTOCOL

The primary endpoint is a pain score using a visual analogue scale for paediatric populations. Pain scores will be recorded on a diary card daily for two weeks post operatively. Diary card data will be collected via a telephone interview at the end of two weeks. Visual analogue scale data will be compared between two groups using a two-tailed t-test where p<0.05 is considered to be statistically significant.

CONCLUSIONS

This double-blinded randomised controlled trial is expected to provide evidence on the safety and efficacy of GeloRevoice™ throat lozenges when used as adjunctive analgesia for post tonsillectomy pain.