A Multicentre Randomized Controlled Trial of two interventions to manage dry mouth inpre-operative elective surgical patients.

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Background

Dry mouth, associated with thirst from fasting, stress, anxiety and pharmacological agentshas been identified to be the most common perioperative complaint. The first Sprint National Anaesthesia Project (SNAP-1) identified thirst as the most prevalent type of severe discomfort post operatively (18.5%) (1).

The PREM (Patient Reported Perioperative Experience Measures) study, a New Zealand observational study investigating the satisfaction and quality of patient recovery following anaesthesia, found 60% of patients reported moderate to severe thirst.

Dry mouth, is amenable to a number of therapies including saliva substitutes, saliva stimulants and intravenous sialogues(2). Most of these have been researched in oncological patients following head and neck surgery or radiotherapy and in patients with autoimmune conditions such as Sjogren's syndrome (3, 4). To date, the efficacy of these treatments has not been tested in the perioperative setting.

To test efficacy of treatment, we will investigate preoperative patients as dry mouth to avoid confounded by intraoperative fluid losses and replacement, use of antisialogue medication and pain.

A local feasibility randomised controlled trial pilot study of 100 participants conducted at Auckland Hospital demonstrated successful recruitment rate, acceptability of interventions and generated data completeness. In addition the protocol was deemed to be easy to use and implemented with just a handful of investigators and assistants.

Aims

1. To assess the efficacy of two interventions to reduce the sensation of dry mouth associated with thirst in pre-operative patients.
2. To assess for any harm that may occur as a result of the interventions.

Methods

Study Design

Prospective, single-blind multicentre randomised controlled trial (RCT).

Ethics

National Health and Disability Ethics Committees (HDEC) approval will be sought.

Participant eligibility criteria

Inclusion criteria

- Elective adult surgical patients (≥ 18 years of age) who:
    - Are able to consent to participate AND,
    - Have complied with local hospital fasting guidelines.

Exclusion criteria

- Patients who did not comply with fasting guidelines.
- Patients undergoing acute surgery.
- Patients who do not give or cannot give consent to participate.

Setting
Multicentre at sites with SATURN affiliated trainees. Sites will be health care facilities providing care for patients immediately prior to elective surgical procedures.

Blinding
Single blinded. The outcome assessor will be blinded to group allocation. The participant and research team or staff delivering the intervention will be unblinded.

Recruitment and Consent
Patients identified to fulfil the inclusion criteria will be approached by the recruiting anaesthetist and be given the study information sheet. If patients agree to participate in the study, consent will be sought by recruiting anaesthetist. A recruitment log will be kept. Recruitment will cease when the target number of participants have been recruited.

Intervention
Each patient will receive either 15ml of water or 15mls of saliva substitute (Biotene Dry Mouth Oral rinse - Glycerin, Xylitol, Sorbitol, Propylene Glycol). The patient is allowed to rinse their mouth for as long as they like and then spit out the liquid.

Randomisaton
Each surgical site will undergo block randomization in groups of 8, with an intervention ratio of 1:1. Randomisation will be concealed by opaque sealed envelope.

Data collection
Baseline characteristics including patient demographics (age, sex, ethnicity, co-morbidities using the Charlson co-morbidity index, regular medications) and operation details (operation, ASA) will be collected.

A pre-intervention questionnaire to assess mouth dryness using a 100mm visual analogue scale (VAS) will be given to patient prior to randomisation to intervention.

At 30 minutes post intervention, patient will be given astandardised post-intervention questionnaireincluding the following:

- 'How did your dry mouth feel after the treatment?' (much worse, worse, no change, better or much better)
- 'Would you have the treatment again?' (yes, no)
- 100mm VAS

Data on harm related to the interventions will be collected.

Primary outcome
Absolute risk reduction in mouth dryness represented by rating of mouth dryness on a 5 point Likert scale post intervention (much worse, worse, no change, better or much better).

Secondary outcomes
Difference in mouth dryness before and after intervention; using a 100mm Visual Analogue Scale (VAS).
Incidence of harm related to interventions.

Sample size

From our feasibility study, using the event rate of 0.62 (P_A) in the intervention group and 0.52 (P_b) in the control group with the assumption of a 10% drop out rate, a sample size of 838patients would provide 80% power to detect an absolute risk reduction of 10% with α=0.05. Using a sample size calculation with 0.57 (P_A) in the intervention group and 0.47 (P_b) in the control group, 854 randomised patients would provide 80% power to detect a relative risk reduction of 10% with α=0.05.

Data monitoring

An independent Data Monitoring Committee (DMC) will be responsible for monitoring the safety and efficacy of data collection and reviewing trial conduct at all recruiting sites and make recommendations to the trial committee.

Statistical Methods

Scientific outcomes will be described with simpleinferential statistics.All analysis will be carried out with intention to treat rather than per protocol. Primary outcome data will be analysed using Chi-squared tests. A p value <0.05 will be taken as significant. Secondary outcome data will be analysed using a t-test with p values and confidence intervals. A p-value <0.05 will be taken as statistically significant.

Subgroup analysis of the following groups for the primary outcome will be undertaken:

- Duration of fluid fasting (<4 hours, 4-8 hours, >8 hours)
- Age (<65 years, >65 years)
- Ethnicity (European, Asian, Maori, Pacific Island)
- Sex (Female, Male)
- Regular medications (eg. Antidepressants, diuretics)
- Use of carbohydrate drinks (yes, no)

References

1. E. M. K. Walker MB, T. M. Cook, M. P. W. Grocott, S. R. Moonesinghe. Patient reported outcome of adult perioperative anaesthesia in the United Kingdom: a cross-sectional observational study. BJA 117 (6). 2016:758–66.

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4. K, Puntillo. A Randomized Clinical Trial of an Intervention to Relieve Thirst and Dry Mouth in Intensive Care Unit Patients. Intensive Care Med. 2014 40(9):1295-302.