SWAT 204: Comparison of bottle weighing versus electronic monitoring to assess adherence to eye drops in a randomised trial.

Objective of this SWAT
To explore if bottle weighing is a suitable method to monitor adherence to topical ocular medication in a randomised trial.

Study area: Adherence, Data Quality, Monitoring
Sample type: Participants, Patients
Estimated funding level needed: Low

Background
Adherence to the allocated medication is an important consideration for randomised trials. Poor adherence may compromise the trial results. There are several ways to evaluate adherence, including quantification of unused medications by trial participants and electronic monitoring.

In the CHAMP-UK trial (ISRCTN99883695), children need to use one drop of either low dose atropine (0.01%) or placebo eye drops in each eye every day for two years. This Study Within a Trial (SWAT) will determine whether bottle weighing would provide an effective alternative to an electronic monitoring method to identify non-adherent participants.

Interventions and comparators
Intervention 1: Electronic adherence monitoring data captured from a Medical Events Monitoring System (MEMS). The MEMS cap is a plastic container with a screw top in which the eye drop bottle is stored until needed for drop instillation.[1,2,3] An electronic record is made of the date and time that the top is unscrewed, and this is taken as a surrogate for administering the medication. The research team will supply participants with a MEMS device when they join the study to store their in-use bottle of eye drops. Participants are told how the MEMS works (including that it will record when the bottle is opened and that this is being taken as a measure of them taking their eye drops) and are trained in how to use it correctly. The MEMS device has previously been tested to measure adherence with eye drops in adults and children with glaucoma.[4] The event logs will be extracted from the MEMS during visits (every six months) via a device connected to a computer. Adherence will be assessed as the percentage of days on which a dose was taken, and on which the correct number of doses was taken. Data will also be extracted on the time of day the MEMS cap was opened to determine the time of drug administration. This information will be used to examine the impact of the time of administration.
Intervention 2: A consecutive sample of eye drop bottles (n=100) will be weighed on calibrated scales in the pharmacy department in one of the participating sites (Victoria Pharmaceuticals, Belfast).

Index Type: Method of Monitoring, Adherence,

Method for allocating to intervention or comparator
Consecutive

Outcome measures
Primary: Identification of non-adherence participants using bottle weighing, defined as those who used less than 80% of eye drops, according to the electronic monitoring system.

Analysis plans
A statistical analysis plan will be developed and approved before data analysis.

Possible problems in implementing this SWAT

References
1. Robin AL, Novack GD, Covert DW, et al. Adherence in glaucoma: objective measurements of once daily and adjunctive medication use. American Journal of Ophthalmology 2007;144:533-40.

2. Sleath B, Blalock S, Covert D, et al. Validation of a short version of the glaucoma medication self-efficacy questionnaire. British Journal of Ophthalmology 2012;96:258-62.
3. Barker GT, Cook PF, Schmiege SJ, et al. Psychometric properties of the Glaucoma Treatment Compliance Assessment Tool in a multicenter trial. American Journal of Ophthalmology 2015;159:1092-9.
4. Freedman RB, Jones SK, Lin A, et al. Influence of parental health literacy and dosing responsibility on pediatric glaucoma medication adherence. Archives of Ophthalmology 2012;130:306-11.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 4/JAN/2018
Revisions made by:
Date of revisions: