SWAT 170: Assessment of clinical utility of the Navio web-based app in protocol adherence and PRO completion in the HoT trial

Objective of this SWAT
To compare completion of patient-reported outcome (PRO) questionnaires with a web-based app (mobile phone/tablet) developed by Navio Theragnostics Inc. versus completion of paper questionnaires by patients in the HoT clinical trial.

Study area: Outcomes
Sample type: Participants
Estimated funding level needed: Unfunded

Background
In many clinical trials, patients complete patient-reported outcomes (PROs) whilst they are attending clinic for their routine (or protocol) follow-up visit. They are often given paper forms, which they complete either before they see the clinician or after the consultation. PRO adherence is variable, but it is common for 20-30% of patients to not complete the questionnaire (e.g. because of insufficient time). In addition, some patients only partially complete the questionnaire so there are missing values which cannot be captured once the patient leaves the clinic. With early stage (curable) cancers, the frequency of assessments and clinic visits is not as often as for advanced disease (e.g. every 6 months instead of every 2-4 months), and the number of assessments usually decrease after the first one or two years. If the expected clinic visits are only every 6 or 12 months, there can be 'slippage' when patients actually attend 2-3 months later and not on time.

The HoT Trial is a multi-centre randomised non-inferiority phase III trial comparing clinical and patient-reported outcomes in patients with low-risk thyroid cancer receiving total thyroidectomy or hemithyroidectomy. The Navio software platform ('Navio app') is being used in the study to support patient adherence to the protocol specified schedule of study visits and for patient-reported outcome (PRO) completion. The Navio app is designed to support patients in clinical trials throughout their treatment by providing educational tools, treatment calendars, and reminders for appointments and to complete patient-reported outcomes. This SWAT will evaluate whether using the Navio app will lead to PRO completion rates that are at least as high as standard procedures, and with fewer missing data items. Even if the completion rate is similar to that seen when patients complete paper forms while in clinic, this would be beneficial because it means that patients can complete the PRO at home and do not have to wait an extra 45-60 minutes in clinic. We will also assess whether use of the Navio app will improve protocol adherence (i.e. timely attendance for the protocol specified schedule of study visits).

The SWAT will be carried out in two phases to evaluate the utility of the web-based app for the collection of PRO data in this clinical trial context. The first phase will be observational in which the first 30-50 patients recruited to the HoT trial and who consent to using the Navio app, will complete the questionnaires in the app using their mobile phone/tablet. Patients who choose not to participate in this sub-study will complete paper QoL/VHI (Voice Handicap Index) forms. QoL/VHI data obtained at baseline, 2-4 weeks post-surgery and at the 6-month visit will be examined. Variables such as time taken to complete the QoL/VHI questions, number of missing data items, number of missing whole forms, and any software issues will be analysed and may prompt revisions before the second phase. In the second phase, up to 406 patients (the remainder of the target sample size for the host trial) will be asked to consent to use the app, and those who do will be randomised to use the app or to use paper QoL/VHI questionnaires to be completed in clinic (control arm).

Interventions and comparators
Intervention 1: SMS messages to remind the patient to complete the PROs at the protocol specified timepoints. The patient will follow a link from the SMS message to login into the Navio app and then be directed to the required PROs for completion. This can be from a mobile phone or tablet and can be done directly from the patient's home.
Intervention 2: Paper-based PROs to be completed by the patient while waiting in clinic.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Percentage of patients who complete the questionnaire, at each of baseline, 2-4 weeks post-surgery, 6-month and annual visits
Secondary: • Percentage of questions completed (per patient) for each questionnaire • Timeliness of questionnaire completion via timestamp of form completion relative to the due date • Number of prompts/reminders required before questionnaire completion • Time taken to complete the questionnaire • Number of times a patient engages with the app

Analysis plans
This SWAT will have a non-inferiority design based on an expected (optimistic) 85% of patients completing the PRO on paper, and a fall to 77.5% (maximum allowable margin of 7.5 percentage points) when using the Navio app. With 10% one-sided statistical significance, 350 patients would have 75% power and 300 patients would have 70% power to assess this.

Possible problems in implementing this SWAT
Patients declining consent to the SWAT or not engaging with the app for PRO completion. These are endpoints for the SWAT, which will be used to assess the clinical utility of the app.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Revisions made by:
Date of revisions: