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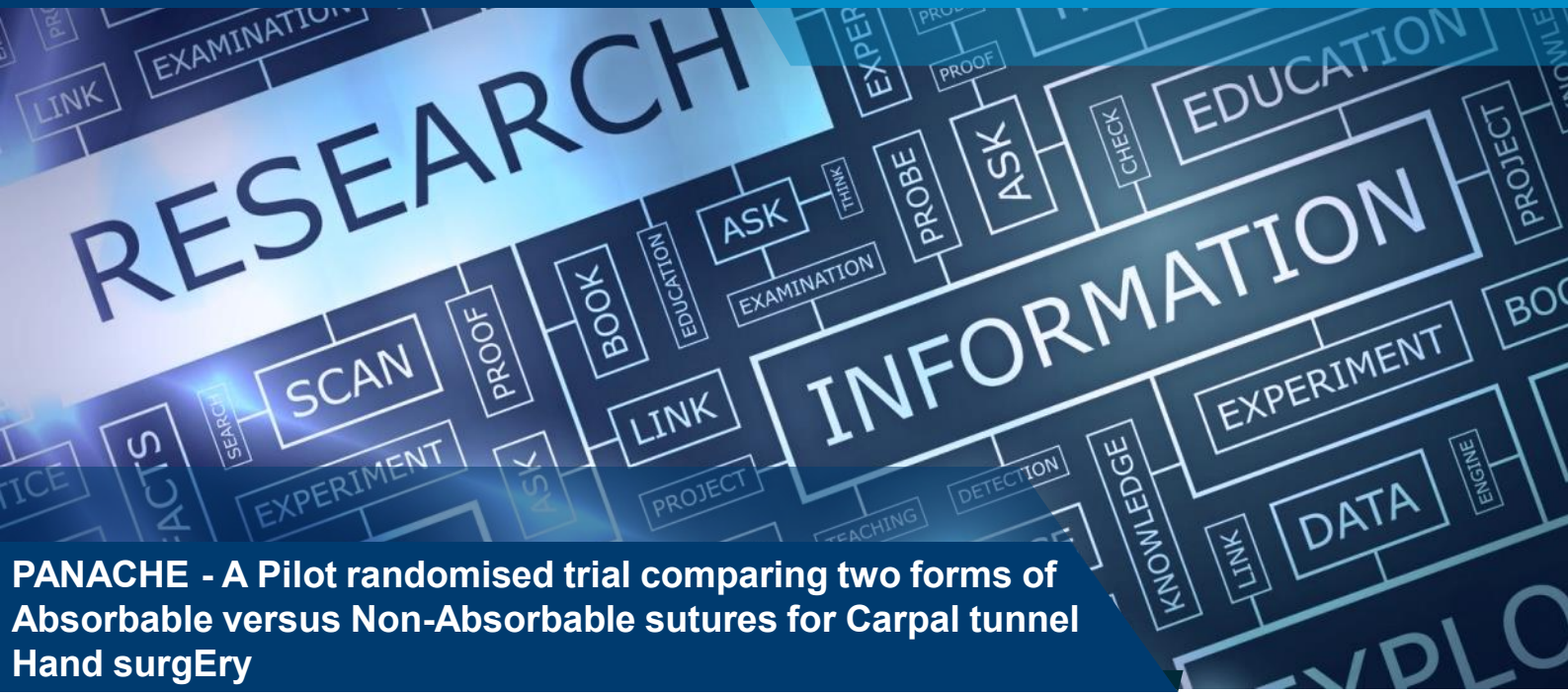
RESEARCH PROJECT BRIEFING



PANACHE - A Pilot randomised trial comparing two forms of Absorbable versus Non-Absorbable sutures for Carpal tunnel Hand surgEry

AIMS

Panache was a pilot randomised controlled trial within NHS Lothian, Fife and Tayside, which assessed closing carpal tunnel surgery wounds with three different types of sutures (2 x absorbable and 1 x non-absorbable suture types). The purpose of this pilot trial was to guide the design of a full trial and establish if it is feasible, in terms of patient recruitment, retention, acceptability of the interventions and compliance with follow up. Knowing whether absorbable sutures are at least as good as non-absorbable sutures would benefit patients and the NHS, because absorbable sutures do not need a procedure and a clinic appointment for suture removal and may be more convenient for patients as well as less costly to the NHS.

KEY FINDINGS

- The trial was recruitable, with 59% (95% CI 51-67%) of eligible and approached patients agreeing to be randomised, higher than predicted.
- 11.7 patients per site per month were recruited, 70% of the target of 16.7 patients per site per month. This will need to be taken into account when calculating the length of a larger trial.
- Early compliance was good at 2 weeks post-surgery (98%) but fell to just above 50% at 6 weeks and 3 months, 40% at 6 months. Some patients expressed concerns about keeping track of the questionnaire packets and returning them at the correct times.
- Where returned, questionnaires were nearly all complete.
- Median differences in the scores of Boston Carpal Tunnel Syndrome Questionnaire, which helps assessing hand symptoms and function, and of patient wound check experience suggest earlier return to normal function in patients with the two absorbable sutures.
- The trial was acceptable to patients, with the majority finding the information easy or very easy to understand (77%), while only one patient found it quite difficult. Only 15 (17%) patients expressed having concerns when deciding to take part in the research, mostly on the practicalities of the follow up questionnaires and diaries.

WHAT DID THE STUDY INVOLVE?

PANACHE is a three-arm pilot multicentre trial, based at three Health Boards in Scotland, that tested if a future definitive trial comparing the outcomes of wound closure after carpal tunnel surgery with absorbable vs. non absorbable sutures is feasible and how it would be best designed. Eligible patients were mailed information about the study, enrolled on the day of surgery, and underwent randomisation to one of three suture types for wound closure (1 non-absorbable and 2 absorbable with different properties). They were followed up in person at two weeks, and asked to return questionnaires at 6 weeks, 3 and 6 months via post, exploring surgery outcome, scar quality, wound healing, complications, return to activities, health-related QoL, NHS healthcare resource use, as well as experience with the participation in the study and barriers to carrying out a definitive study. Questionnaires vs. Diaries were explored as means of collecting data on events, complications and return to activities. Text messages were utilised at each postal follow up as a reminder. Questionnaires and an interview were also administered to participating investigators to explore their experience with the trial. A panel of carpal tunnel surgery patients and some surgeons were involved in the design of the study, assisting in the optimization of questionnaires and defining the follow up strategy that was explored.

WHAT WERE THE RESULTS AND WHAT DO THEY MEAN?

During the 3 months of recruitment, 215 patients were screened, 151 were found to be eligible (70%); of those eligible, 89 were randomised (59%, 95% CI 51, 67%). This exceeds the target of 50% for proceeding to a full-scale trial. Baseline compliance was 100%, with good retention at 2 weeks (97.7%). However, follow up at 6 weeks and 3 months was only just above 50%, with 6 month follow up at 40%.

Patient diaries were returned at the 6 month follow up, and return rates were similarly low (36%). The management of follow up will need to be assessed and adjusted prior to a full-scale trial. Rather than allowing patients to return home with a complete set of follow up questionnaires (up to 6 months), alternative methods of engagement will be considered. Patients found information received on the trial very or quite easy to understand, and 78.1% had no concerns with participating. Patients found questionnaires an easy instrument, while some raised difficulties with the use of diaries. Qualitative research analysis supported use of questionnaires over diaries and collected an overall positive experience from participating investigators but highlighted an advantage in having stronger local administrative/research team support.

Outcome scales were measured on wound healing, scar quality, functional changes, health-related quality of life. The trial was not powered to detect differences in any of these outcome scales, they were included to a) confirm the usability and acceptability of the measures, and b) to gain estimates of the variability within this population to inform a larger trial.
There was no strong evidence of a difference between the groups in the Southampton Wound Score at 2 weeks, although there were fewer patients with redness + other signs of infection in the absorbable groups. Responses to the patient wound check experience questionnaire suggested better patient-rated recovery from surgery, slightly lower level of concern about coming to the appointment and level of discomfort experienced at the appointment among

both absorbable suture groups vs the non-absorbable suture group but this was at the visit where the non-absorbable sutures would have been removed. The Patient and Observer Scar Assessment Scale (POSAS) also suggested a slightly better overall scar outcome in the absorbable sutures groups. No large differences between groups were seen in preliminary direct intervention related cost estimates although unscheduled care costs were lower in the absorbable suture groups. The Health-related Quality of Life (EQ-5D-5L) questionnaire suggested an improving trend in quality of life over time across all arms with best improvement trajectory and final health utility scores in one of the absorbable suture groups.

WHAT IMPACT COULD THE FINDINGS HAVE?

The results of PANACHE will allow better definition of endpoints and recruitment targets of a definitive trial of wound closure after carpal tunnel release, and the identification of strategies to improve compliance and retention in the follow up, for example posting questionnaires close to timepoints, using online questionnaires, adopting telephone calls as reminders rather than texts

PANACHE demonstrated the feasibility of the collection of key health economic data needed to permit a cost-effectiveness assessment of the intervention/s in a future definitive trial.

PANACHE has documented investigator and patient support for a definitive trial which will help strengthen a grant application

The feasibility testing of this trial can be valuable in the design of future trials in hand surgery

HOW WILL THE OUTCOMES BE DISSEMINATED?

The results will be published in the form of a lay abstract on the Edinburgh Clinical Trial Unit website, will be summarized in a manuscript that will be submitted for publication in a peer review journal in the field of hand surgery, and will be submitted for presentation to a national-level hand or plastic surgery conference. The results will be shared with the PPI group involved in the design of the study who will help with dissemination to the wider public.

CONCLUSION

This trial demonstrates that it is feasible and practical to take this research to a larger scale trial. The follow up aspects that were trialled (questionnaires, timing and the questionnaire packet) have given us insight into the practicalities that will need to be incorporated into a larger trial.

RESEARCH TEAM & CONTACT

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Additional Information

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