

Quality assurance within multicentre randomised controlled trials of surgical interventions for pancreatic cancer: Protocol for a systematic review



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Introduction

- **Quality assurance** mechanisms aim to ensure standardisation of surgical techniques. A lack of consideration of quality assurance risks the introduction of **performance bias** and **limits the ability to contextualise results**.
- The quantity and quality of pancreatic RCTs has increased over the last three decades. However, there has been **no previous assessment of quality assurance measures in this setting**.

Aim

- To identify **approaches to quality assurance within multicentre trials of surgical interventions** for pancreatic cancer.
- To explore the effect of such quality assurance measures on post-operative outcomes.

Methods

- A **systematic review** will be performed. MEDLINE and Embase databases were searched between 1st January 2000 and 18th October 2022.
- Articles will be eligible for inclusion if they: i) comprise a **multi-centre, randomised controlled trial** study design, ii) evaluate a **surgical intervention or variation in the approach to curative surgical resection/ reconstruction** for pancreatic cancer.
- Outcomes of interest will include: operation type, number of centres, number of surgeons performing the intervention and measurement of surgical quality assurance.

Discussion

A total of **1970 papers** will be inspected

- A finalised checklist for the measurement of surgical quality assurance within pancreatic RCTs has been developed by way of consensus opinion within the study group.
- The checklist comprises three domains:
 - (1) Standardisation of surgical technique**
 - (2) Methods of credentialing surgical experience**
 - (3) Methods of monitoring performance**
- Results relating to the use of this checklist will be presented and correlated with associated clinical outcomes.

KEY MESSAGE

This study will provide:

- 1** Important data on the utilisation of methods for surgical quality assurance within pancreatic RCTs.
- 2** Insight into how future studies may implement surgical quality assurance measures to reduce variability of surgical performance and potential bias.