

ROCSS trial

ROCSS: Reinforcement of Closure of Stoma Site. A randomised controlled trial of reinforcement of closure of stoma site using a biological mesh.

ROCSS is a randomised controlled trial assessing the placement of biological mesh in order to reduce the rate of hernias at the site of stoma closure. Strattice is a well-established biological mesh/ tissue matrix which would be compared against a control arm of no mesh placement.

The Rationale for a Trial

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Closure of complex and contaminated abdominal wounds is challenging and carries risks, including wound dehiscence and incisional hernias. Use of biological meshes in these situations may provide a safe method of reducing these complications, especially long-term incisional hernias. ROCSS will use stoma site closure as a model for biological mesh placement during any difficult contaminated abdominal wall closures.

Hernia at the site of stoma closure occurs in up to 30% of patients and is associated with adverse effects on quality of life. In up to 10% of cases, patients are submitted to complex re-operation which carries significant morbidity. Not all patients will report symptoms or undergo repair, as they do not wish to have a further major operation. Incisional hernias at the site of stomas closure form an important and well defined subgroup. If there is a measurable benefit from mesh insertion, elective use of a collagen mesh would warrant consideration in the closure of other difficult, contaminated abdominal wounds. This study will also provide useful information on the value of using a CT scan as an early diagnostic tool of herniation, which could then be used in future abdominal wall studies as a surrogate endpoint for clinical hernia.

The aim of the ROCSS trial is to assess whether a biological mesh (collagen tissue matrix) reduces the incidence of clinically detectable stoma closure site hernias at two years compared to standard closure techniques.

Trial Design

ROCSS is a prospective, multi-centre randomised controlled trial.

ROCSS is designed in two stages:

- i) a feasibility study
- ii) a Phase III multi-centre RCT

The feasibility phase will assess recruitment, the randomisation process and deliverability of the treatment.

The Phase III study will be a prospective, multi-centre RCT to determine if the use of a collagen tissue matrix (Strattice®) reduces the incidence of clinically detectable stoma closure site hernias at two years as compared to standard closure techniques.

The trial aims to randomise 560 patients in 2 years.

Objectives

Objectives of the feasibility trial

- To develop strategies for effective recruitment and randomisation
- To assess the deliverability of the mesh placement technique.

Objectives of the main trial

Primary objective:

- To assess whether a collagen tissue matrix (Strattice) reduces the incidence of clinically detected stoma closure site hernias at two years compared to standard closure techniques.

Secondary objectives:

To assess:

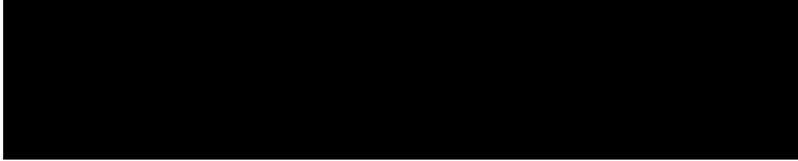
- Frequency of wound infections and seroma associated with the mesh.
- Patient quality of life and pain experienced.
- Cost effectiveness of the mesh insertion in stoma site closure and management of subsequent hernias.
- Exploratory analysis to investigate the CT scan as an early surrogate marker of late clinical herniation:
- Radiological hernia rate at one year post closure will be compared with the clinical hernia rate at 2 years to assess the value of using a CT scan as an early diagnostic tool of herniation

ROCSS Trial Surgical Technique

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Outcome Measures

Primary outcomes:

- Occurrence of clinically detected hernias at two years post closure

Secondary outcomes:

- Radiological hernia rate at one year post closure. An exploratory analysis will compare radiological hernia rate at 1 year with clinical hernia rate at 2 years to assess the value of using a CT scan as an early diagnostic tool of incisional hernias
- Surgical re-intervention rate
- Surgical complications at 30 days and 1 year
- Quality of life and post-operative pain
- Cost-benefit analysis

Randomisation

To randomise a patient please call **0800 953 0274**

We will soon have an online application and we will let you know as soon as we go live.

ROCSS Study Office

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