

A study to assess tissue health in patients undergoing orthopaedic surgery using a surgical humidification system

ACTRN12625001110471

Status	RECRUITING
Sponsor	Fisher and Paykel Healthcare Ltd.
Enrollment	20 participants

Plain Language Summary

When the body is opened during surgery, the tissues are exposed to the cool, dry air of the operating theatre — quite different from the warm, moist environment they are used to inside the body. This can cause the surgical wound to lose heat and dry out, potentially harming the tissue and increasing the risk of wound infection. Surgical humidification — blowing warm, moist air over the open wound — has been shown to help in abdominal and heart surgeries, but has not yet been studied in spinal surgery.

This trial will test a device called HumiGard, which delivers warm humidified gas to open spinal wounds during surgery. After the operation, tissue samples taken from the wound will be examined under a microscope to see whether the tissues are healthier in patients who received the humidification treatment.

You may be eligible if you are 22 years or older, are scheduled for a planned (non-emergency) open posterior spinal surgery lasting at least two hours, and are able to give written consent. People having revision (repeat) spinal surgery or procedures requiring multiple incisions or very long incisions (over 260mm) are not eligible.

Key Eligibility Criteria

Inclusion (3)

- Patients undergoing primary elective posterior spinal surgery lasting at least 120 minutes
- Patients aged 22 years and older
- Patients able to provide written informed consent

Exclusion (4)

- Individuals are excluded from participating in this study if:
- Surgical procedure requires incision length greater than 260mm
- Surgical procedure requires multiple incisions
- Patient is undergoing a revision spinal surgery procedure

Locations (1 total)

Hamilton, New Zealand

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625001110471>

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