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Does an absorbable poloxamer and sodium alginate gel applied during lower-back (lumbar) spine surgery reduce scar tissue and improve recovery?

Submission date
05/06/2026

Recruitment status
No longer recruiting

Registration date
08/07/2026

Overall study status
Completed

Last Edited
15/06/2026

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Comparison of clinical and radiological outcomes in patients undergoing lumbar spine surgery with versus without an intraoperative poloxamer and sodium alginate-based barrier agent (Guardix-SG): a randomised controlled trial

Study objectives
To compare clinical outcomes (low back pain VAS, leg pain VAS, Oswestry Disability Index) and the radiological outcome (severity of epidural fibrosis on MRI) between patients receiving an intraoperative poloxamer and sodium alginate barrier agent (Guardix-SG) versus no barrier agent after lumbar spine surgery.

Hypothesis: the barrier agent improves clinical outcomes and reduces epidural fibrosis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/07/2025, Ethics committee of Rumah Sakit Universitas Indonesia (Jl. Prof. Dr. Bahder Djohan, Pondok Cina, Kecamatan Beji, Kota Depok, Jawa Barat, Depok, 16424, Indonesia; +62 (0)212150829292; kep@rs.ui.ac.id), ref: 2025-06-109

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Patients undergoing lumbar spine decompression surgery (with or without stabilization); prevention of postoperative epidural fibrosis/failed back surgery syndrome

Interventions
Intervention arm (n = 10):
Standard lumbar decompression (with or without instrumentation). At the end of surgery, after decompression/instrumentation, haemostasis, warm saline irrigation and suction to dryness, one 3 g syringe of Guardix-SG per decompression level is applied directly over the dura mater, moving from the cranial edge of the laminectomy defect caudally to cover the dura, nerve roots and epidural space. The gel is left for 15–30 seconds to set; the field is not re-irrigated afterwards; any drain is placed laterally, away from the gel; the wound is closed in layers.

Control arm (n = 10):
Identical standard lumbar spine surgery without any barrier agent.

Allocation by random number table (1:1).

Surgery is performed by consultant spine orthopaedic surgeons. Participants and outcome assessors blinded; operating surgeon not blinded. Clinical follow-up at 1, 3 and 6 months; contrast-enhanced MRI at 6 months. Analysed by intention-to-treat.

Intervention Type
Drug/Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Guardix-SG (cross-linked poloxamer + sodium alginate + calcium chloride; manufacturer Genewel /Dongsung Co., Seongnam, Republic of Korea)

Primary outcome(s)
1. Low back pain and leg pain measured using the Visual Analogue Scale at preoperative baseline and 1, 3 and 6 months postoperatively

2. Disability measured using the Oswestry Disability Index at preoperative baseline and 1, 3 and 6 months postoperatively

3. Severity of epidural fibrosis measured using contrast-enhanced (gadolinium) T2 axial MRI, graded 0–4 across four quadrants on five consecutive slices and averaged (Ross-type grading), at 6 months postoperatively

Key secondary outcome(s)

1. Postoperative complications measured using any deviation from the normal postoperative course at through 6 months

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Undergoing lumbar decompression surgery (with or without stabilisation) at the participating hospitals during the study period
2. Aged 18 years or older
3. Willing to participate in the study (provided consent)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. History of previous spine surgery
2. Immune disorder or autoimmune disease
3. Spinal malignancy

Date of first enrolment
29/07/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Indonesia

Study participating centre
Dr. Cipto Mangunkusumo Hospital
Indonesia

Study participating centre
Fatmawati Hospital
Indonesia

Study participating centre
Universitas Indonesia Hospital
Indonesia

Sponsor information

Organisation
University of Indonesia

ROR
https://ror.org/0116zj450

Funder(s)

Funder type

Funder Name
Fakultas Kedokteran, Universitas Indonesia

Alternative Name(s)
UI's Faculty of Medicine, Faculty of Medicine, University of Indonesia, Faculty of Medicine UI, Faculty of Medicine, Universitas Indonesia, Faculty of Medicine Universitas Indonesia, Fakultas Kedokteran Universitas Indonesia, Fakultas Kedokteran - Universitas Indonesia, Fakultas Kedokteran UI, KedokteranUI, FKUI, FMUI

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location

Indonesia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available