

Chang Gung Medical Foundation, Linkou Chang Gung Memorial Hospital

Informed Consent Form

- This Informed Consent Form has been reviewed and approved by the Institutional Review Board (IRB) of our institution. Any future revisions must also be approved. The Principal Investigator or designated research personnel must personally explain the study in detail. Please read carefully before signing.

1. Study Title: A Prospective Investigation of Outcomes Following Duroplasty in Patients Undergoing Surgery for Traumatic Spinal Cord Injury with Uncontrolled Spinal Cord Swelling	
2. General Study Information	Medical Record Number: _____
1. Study Code: IRB Approval Number: 2312250059	
2. Investigational Site: Linkou Chang Gung Memorial Hospital	
3. Department: Department of Neurosurgery	
4. Sponsor: Linkou Chang Gung Memorial Hospital	
5. Principal Investigator (PI): Dr. Ying-Ching Li Title: Assistant Professor-level Attending Neurosurgeon (Spine) Phone: 0978-835-535 Co-Investigator: Prof. Yu-Jen Lu Phone: 0975-365-510 Emergency Contact (24-hour): 0978-835-535	
6. Participant Name: _____ Research ID: _____ Sex: _____ Age: _____ Phone: _____	
3. Concise Summary (Key Information) You (or your family member) are invited to participate in a clinical research study evaluating whether adding duroplasty to standard decompressive surgery improves functional outcomes in patients with acute traumatic spinal cord injury complicated by uncontrolled spinal cord swelling. Current standard treatment is laminectomy (decompression). This research investigates whether additional expansion of the dura (duroplasty) may improve neurological recovery at 6 months. If you agree to participate: • 50% chance = experimental arm (laminectomy + duroplasty) • 50% chance = control arm (laminectomy alone) Participation lasts 6–12 months with continued follow-up for up to 2 years. You may choose not to participate without affecting your medical care.	
4. Study Purpose This study aims to determine whether duroplasty provides additional benefit beyond standard decompression by improving muscle strength and neurological function. If proven effective, duroplasty may become part of standard care for severe cervical spinal cord injuries, potentially reducing long-term disability and healthcare burden.	
5. Inclusion and Exclusion Criteria Inclusion Criteria 1. Age ≥ 18 years 2. Severe traumatic cervical spinal cord injury (C2–T1), AIS grades A–C 3. Surgical indication requiring laminectomy and/or discectomy 4. Surgery within 72 hours of injury Exclusion Criteria 1. Comorbidities limiting recovery or affecting daily life 2. Thoracic or lumbar traumatic spinal cord injury 3. Other central nervous system disorders	

6. Study Procedures

1. We will enroll 104 adult patients with acute, severe traumatic cervical spinal cord injury over 2 years.
2. Total participation duration is 24 months.
3. Participants will be randomized 1:1 into:
 - Experimental: laminectomy + duroplasty
 - Control: standard laminectomy
4. At 6 months, motor function will be assessed (grasping, ambulation, sphincter function). Duration ~20 minutes.
5. Patient-reported outcome questionnaires (3, 6, 12 months) require ~10 minutes.
6. We will collect clinical data, MRI images, operative notes, medications, and rehabilitation records.
7. If clinically permitted, MRI will be performed on postoperative days 7 and 14 to assess cord edema and decompression.

7. No biological specimens are collected.

8. Anticipated Benefits

There may be no direct personal benefit. However, findings may:

- Improve future treatment planning
- Advance understanding of cord edema and decompression
- Benefit future patients

Standard care will still be provided even if you decline participation.

9. Anticipated Risks, Side Effects, Incidence, and Management

There is a known risk that duroplasty may lead to asymptomatic cerebrospinal fluid (CSF) leakage from the surgical wound or the formation of a pseudomeningocele. CSF leakage can typically be effectively managed with lumbar drainage for approximately 5 to 10 days. Most pseudomeningoceles resolve spontaneously; however, according to international reports, approximately 1% of patients may require revision surgery to repair the defect. Literature also reports an approximately 1% risk of postoperative infection; therefore, prophylactic antibiotics will be administered to reduce this risk. In patients with pseudomeningocele, there is an approximate 9% risk of developing aseptic meningitis.

To minimize postoperative CSF leakage and pseudomeningocele, patients will be advised to maintain a 45-degree supine position for one week to reduce cervical CSF pressure.

1. **Physiological Impact:** None anticipated.
2. **Psychological Impact:** None anticipated.
3. **Social Impact:** Potential social risks resulting from unauthorized disclosure of personal data—such as effects on education, employment, healthcare access, or insurance—cannot be fully predicted. The Principal Investigator is responsible for safeguarding participant data to prevent such occurrences.
4. **Management Measures:** The Principal Investigator must ensure the protection and confidentiality of participant information to prevent unauthorized disclosure.

10. Alternative Treatment Options

You may choose not to participate in this clinical study and instead receive the standard course of treatment. Declining participation will not affect your rights, access to medical care, or any other personal benefits in any way.

11. Contraindications and Restrictions of This Study

Magnetic resonance imaging (MRI) is a time-consuming examination. If the patient is unable to appropriately cooperate during the procedure, the scan may be canceled. MRI is necessary to allow the treating physicians to clearly evaluate the degree of neural decompression and the severity of spinal cord edema.

12. Expected Study Outcomes

Your participation in this study may not provide direct benefit to you personally. However, according to international research, duroplasty may improve spinal cord decompression. Additional studies are still required to determine the extent of neurological recovery following this procedure. The results of this study

may help physicians better understand the degree of spinal cord edema in traumatic injury and the prognostic impact of decompression achieved through duroplasty. This knowledge may contribute to the development of more appropriate treatment strategies for patients with similar conditions and may ultimately benefit future patients.

13. Management of Emergency Situations

If you experience any neurological deterioration, wound leakage, or other concerning symptoms during participation in this study, please contact the on-call physician immediately for urgent evaluation and management. The Principal Investigator will be notified for further assessment. The 24-hour emergency contact number for the Principal Investigator, Dr. Ying-Ching Li (Neurosurgery), is **0978-835-535**.

14. Compensation, Cost Coverage, and Injury Management

1. **Compensation:**

Participation in this study is voluntary and will not provide monetary compensation.

2. **Cost Coverage:**

You will not be required to pay any costs associated with participation in this study.

3. **Injury Compensation:**

(1) If an adverse reaction or injury occurs as a direct result of the clinical trial procedures described in this study, the hospital will provide compensation in accordance with applicable laws and regulations. However, adverse reactions listed as foreseeable in this consent form are not eligible for compensation.

(2) If an adverse reaction or injury occurs as a direct result of study procedures, the hospital will provide appropriate professional medical care and consultation. You will not be responsible for the necessary medical expenses related to the treatment of such injury.

(3) Beyond the medical care and compensation described above, no additional forms of compensation will be provided. If you are unwilling to accept this potential risk, you should not participate in this study.

(4) Signing this consent form does not waive any of your legal rights.

15. Protection of Privacy and Confidentiality

1. A unique study code will be assigned to represent your identity. This code will not reveal your name, national identification number, address, or any other personal identifiers.
2. The Principal Investigator will maintain strict confidentiality regarding all information collected from interviews, assessments, and medical evaluations. If study results are published, your identity will remain protected and anonymized.
3. By signing this consent form, you acknowledge that authorized monitors, auditors, the Institutional Review Board (IRB), and regulatory authorities may directly access your study records to verify that the research procedures and data comply with applicable laws, regulations, and ethical requirements. These individuals are bound by confidentiality obligations and will not disclose information that could reveal your identity.
4. For safety reasons, the research team may inform or coordinate with your other attending physicians regarding your participation in this study and your medical condition, in order to prevent potential drug interactions or treatment conflicts.

16. Withdrawal and Discontinuation from the Study

You, or the person authorized to sign this consent form on your behalf, have the right to withdraw from this study at any time and for any reason, without penalty. Withdrawing from the study will not affect your legal rights or your access to appropriate medical care. The Principal Investigator or sponsor may also terminate the study if necessary.

For your safety, you must be withdrawn from this study if any of the following conditions occur:

1. **Preoperative Deterioration:** If clinical deterioration occurs after signing the consent form but before surgery, making the planned procedure no longer in the patient's best interest.
2. **Surgical Delay:** If surgery is delayed for more than 72 hours after signing the consent form.
3. **Intraoperative Considerations:** During surgery, if the neurosurgeon determines that duroplasty is inappropriate or cannot be safely performed.



If new information becomes available during the course of the study that may affect your willingness or ability to continue participation, you will be informed and provided an opportunity to reconsider your participation. Your decision to continue or withdraw will not result in any discrimination, unpleasantness, or negative impact on future medical care.

If you withdraw from the study—or if the Principal Investigator determines that continued participation is unsafe—data collected up to the time of withdrawal will be retained and will not be removed. After withdrawal, you may decide how previously collected specimens should be handled and whether you consent to continued collection of additional data by the Principal Investigator or sponsor.

17. Participant Rights

1. With respect to the collection, processing, and use of your personal data, the study institution and the Principal Investigator will comply with this informed consent form, applicable clinical trial regulations, and relevant personal data protection laws. In accordance with these laws, you may exercise the following rights by submitting a written request to the study institution or the Principal Investigator:
 - (1) To inquire about or request access to your personal data;
 - (2) To request a copy of your personal data;
 - (3) To request supplementation or correction of your personal data;
 - (4) To request the cessation of collection, processing, or use of your personal data;
 - (5) To request deletion of your personal data.
2. During the course of the study, any new information that may affect your willingness to continue participation will be promptly provided to you. If you have any questions or concerns regarding the study, you may contact the Principal Investigator at any time.
3. If you have concerns about your rights as a research participant, or believe that you may have been harmed due to participation in this study, you may contact the Institutional Review Board of this institution for consultation at:
(03) 319-6200 extensions 3705–3709, 3711–3713.

18. Ownership of Study Results and Related Rights

If the results of this study lead to academic publication, tangible benefits, or any other derived interests, you agree to donate such benefits without compensation to this institution for purposes related to disease prevention, diagnosis, and treatment in the public interest.

This study is not expected to generate any patents or commercial benefits.

19. Storage and Future Use of Personal Data, Biological Specimens, and Derivatives

All future research projects must be reviewed and approved by the Institutional Review Board (IRB) of the Chang Gung Medical Foundation. If the IRB determines that any new research exceeds the scope of your original consent, additional consent will be required.

1. Personal Data

During the study period, and in accordance with the type of research and the authorization you provide, we will collect relevant information such as your medical records, clinical documentation, rating scales, and questionnaire responses. A unique study identification code will be used to replace your name and other identifiable personal information.

If these data are stored in paper form, they will be kept separately from this consent form in a locked cabinet within the research institution. If stored electronically for statistical analysis, they will be kept on password-protected computers equipped with appropriate security and antivirus software.

All collected data will be retained for up to **three years** after the study is completed, after which they will be destroyed. If your data are transmitted overseas for analysis, protection standards equivalent to local regulations will apply. The Principal Investigator and research team will take all reasonable measures to ensure adequate protection and confidentiality of your personal data.

Please indicate whether you agree to allow your personal data to be preserved for future research use, and to authorize the IRB of the Chang Gung Medical Foundation to determine whether additional consent is required:

☐ (1) I do **not** agree to the storage of my personal data. Please destroy them after the study is completed.

Participant Signature: _____ Date: ____ / ____ / ____



- ☐ (2) I agree to the storage of my personal data in a **de-identified** (non-linkable) format. If future use exceeds the scope of this consent, I must be contacted to provide additional consent.
- ☐ I agree that, after the completion of this study, my personal data may be stored in the Human Biobank of _____ Chang Gung Memorial Hospital, and may be used for future research approved by the hospital's Institutional Review Board. (A separate Human Biobank consent form must also be signed.)
- Participant Signature: _____ Date: ____ / ____ / ____

20. Declaration

1. The contents of this study and this informed consent form have been fully explained verbally to the participant and/or legal representative by:

☐ Principal Investigator ☐ Co-/Sub-Investigator ☐ Other personnel (please provide the following information):

_____ (Printed Name) _____ (Signature) Date: ____ / ____ / ____

(Please check or fill in the name of the person who explained this consent form.)

The participant and/or legal representative has fully understood and agrees to participate.

This informed consent form is prepared in duplicate, and a copy has been provided to the participant.

Signature Page

A. Participant:

Printed Name: _____

Signature: _____ Date: ____ / ____ / ____

B. Co-/Sub-Investigator:

Printed Name: _____

Signature: _____ Date: ____ / ____ / ____

C. Principal Investigator:

Printed Name: _____

Signature: _____ Date: ____ / ____ / ____

****If the participant meets the conditions described in Item (1) of the "Informed Consent Signing Instructions," this field must be signed.**

****The Principal Investigator is responsible for obtaining valid and voluntary consent and must make reasonable efforts to verify the identity of the legal representative / authorized decision-maker / guardian / assistant.**

D. Legal Representative / Authorized Decision-Maker / Guardian / Assistant

I have carefully read the information above, or the information has been read aloud to me by the study staff to ensure my understanding. I have had the opportunity to ask questions regarding this study, and all questions have been answered in detail. As the participant's:

☐ Spouse ☐ Father ☐ Mother ☐ Son ☐ Daughter ☐ Other: _____

I consent for the participant to join this study.

Printed Name: _____

Signature: _____ Date: ____ / ____ / ____

Phone: _____

****If the participant meets the conditions described in Item (2) of the "Informed Consent Signing Instructions," this field must be signed.**

E. Witness:

Printed Name: _____



長庚醫療財團法人
CHANG GUNG MEDICAL FOUNDATION

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版本日期

【2024/05/17 Version5】

Signature: _____ Date: ____ / ____ / ____

【Instructions for Signing the Informed Consent Form】

(1) Conditions for Use of a Legal Representative / Authorized Decision-Maker / Guardian / Assistant

* According to: Medical Care Act Article 79, Human Subjects Research Act Article 12, and Good Clinical Practice (GCP) Article 5:

1. If a participant has no legal capacity (such as a minor under seven years of age or a person declared under guardianship), consent must be provided by the legal representative. For persons declared under guardianship, the guardian serves as the legal representative.
2. If a participant has limited legal capacity (such as a minor seven years of age or older, or a person declared requiring assistance), consent must be obtained from both the participant and the legal representative or assistant.
3. If a participant does not legally lack capacity, but due to conditions such as impaired consciousness, psychiatric disability, or intellectual disability is unable to communicate effectively or make independent judgments, consent may be provided by a legally authorized person.

(2) Conditions Requiring a Witness

* According to GCP Article 21:

1. When the participant, legal representative, or authorized decision-maker cannot read, a witness must be present for all discussions regarding the informed consent process. The witness shall read the consent form and any written information provided, ensuring that the Principal Investigator or delegated research personnel have accurately explained its contents, and that the participant (or authorized representative) fully understands the information.
2. The participant, legal representative, or authorized decision-maker must personally sign and date the consent form. A fingerprint may replace a signature if necessary.
3. After oral explanations are completed, and once the witness confirms that consent is given voluntarily, the witness must sign and date the consent form.
4. Research personnel directly involved in the study may not serve as witnesses.

(3) Consent Order for Legal Representatives

* According to the Medical Care Act Article 79:

Medical institutions conducting human research must exercise necessary medical caution and must obtain written informed consent from the participant. Participation is limited to competent adults, unless the study provides clear benefit to specific populations or individuals with particular diseases.

* According to the Regulations on Human Subject Research Article 5:

For adult participants recruited under the exception clause of Medical Care Act Article 79, or for minors who are married, the Principal Investigator must obtain consent from at least one of the following individuals, in the order listed:

1. Spouse
2. Parents
3. Adult children residing with the participant
4. Grandparents residing with the participant
5. Adult siblings residing with the participant
6. Other relatives who have lived with the participant within the past year

Consent from individuals listed in Items (1) through (5) shall prioritize those currently residing with the participant.

Consent provided by the above representatives may not contradict any previously expressed wishes of the participant.

【Information for Research Participants – Chang Gung Medical Foundation / Chang Gung Memorial Hospital / Chang Gung University / Chang Gung University of Science and Technology】

Dear participant, family member, or community member:

If you meet the eligibility criteria of a research or clinical trial, you may be invited to participate in a study conducted by Chang Gung Memorial Hospital, Chang Gung University, or Chang Gung University of Science and Technology. To protect your safety and rights as a research participant, the following information explains how the Institutional Review Board (IRB) oversees research, how studies are reviewed, and what rights you have as a participant.

What is research?

“Research” is not the same as “treatment.”

Treatment is provided based on knowledge already established through research, including known side effects and risks. Research, however, aims to answer questions that are not yet fully understood, and therefore the outcomes are not completely known.

■ Participation in research is voluntary.

■ Not participating will not affect your medical care, treatment rights, or lead to any unfair treatment.

What is the Institutional Review Board (IRB)?

The Institutional Review Board (IRB) is an oversight committee established to ensure that human research is ethical and scientifically appropriate.

Members include medical professionals as well as non-medical individuals such as:

- legal experts,
- community representatives,
- members of the public.

Their role is to protect your rights, safety, and well-being. If you have concerns about your rights, you may contact the IRB directly.

How does the IRB review clinical research? What are the key considerations?

1. All research conducted at Chang Gung Memorial Hospital, Chang Gung University, or Chang Gung University of Science and Technology must be reviewed and approved by the IRB before it can begin.
2. All submitted studies are reviewed by independent and qualified reviewers.

Key review points include:

- the purpose of the study,
 - study procedures,
 - alternative treatment options,
 - possible side effects, risks, and benefits,
 - how to withdraw,
 - participant privacy and safety protections.
3. The IRB evaluates potential risks, including:
 - physical discomfort or injury,
 - psychological stress,
 - possible social or economic impacts.

The IRB ensures that risks are minimized and are reasonable in relation to expected benefits, such as:

- disease improvement,
- quality-of-life improvements,
- scientific knowledge,
- future treatment innovations.

Studies with risks that outweigh any benefit will not be approved.

4. After approval, both the IRB and the hosting institution will continue to supervise the study to ensure that:
 - the study is conducted as approved,
 - participant rights remain protected.
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What are your rights as a research participant?

You have the right to understand clearly:

1. What is the purpose of the study?
The research team must explain it in understandable language.
2. What will happen to you during the study?
You should know:
 - what procedures or tests will be performed,
 - how often you must return,
 - how much blood is drawn,
 - how the study may affect daily life.
3. Are there other treatment options?
Research participation is not required.
4. What risks or side effects may occur?
You must be informed of:
 - physical or psychological risks,
 - how emergencies will be handled,
 - whom to contact,
 - how medical treatment will be provided,
 - how costs will be covered.
5. What potential benefits may occur?

These may include:

- improvement in condition,
- improved quality of life,
- contributions to future medical advances,
- benefits for future patients.

6. How can you withdraw?

You must know:

- whom to contact,
- how to exit safely,
- whether your data will continue to be analyzed afterward.

7. You may always ask questions.

Your Right to Voluntary Participation

You may take adequate time to decide.

Only after signing the informed consent form do you become a participant.

If you choose to withdraw later:

- You may do so at any time,
 - Without providing any reason,
 - Without affecting your future medical care or legal rights.
-

Your Right to Protection

1. Privacy and confidentiality

Your personal information will be protected.

Regulatory agencies (such as the Ministry of Health and Welfare) and the IRB may review study data to ensure compliance, but your identity will remain confidential during publication or oversight.

2. Retention of legal rights

Participation in research does not require giving up any legal rights you currently have.

