PATIENT INFORMATION SHEET AND INFORMED CONSENT

“Infectious Prophylaxis with Trimethoprim–Sulfamethoxazole Following Severe Acute Kidney Injury: A Clinical Trial at the Old Civil Hospital of Guadalajara, from October 2025 to October 2026”

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What is informed consent?
You are invited to take part in a clinical research study. Before you decide whether to participate, you must understand the possible risks and benefits associated with this study. This process is known as informed consent, which means that you:

• Receive detailed information about this research study, including any benefits and risks of participating;
• Will be invited to read, sign, and date this informed consent form once you understand the study and wish to participate. If you do not understand something or have questions, please be sure to request clarification before signing this form;
• Will be given a signed and dated copy of this consent form.

Your participation in this study is entirely voluntary. You are not obligated to participate. Your current medical care will not be affected by your decision to participate or not. If you choose not to participate, you will not incur any penalty or loss of benefits to which you are otherwise entitled. You must sign this form before any study-related procedures are performed.
Before agreeing to participate, it is very important that you understand the purpose of the study and the types of procedures in which you will be asked to take part. The following

information describes the study and your role within it. You may take a copy of this form to review at your convenience and seek advice from others before signing.

What is the purpose of this study?
Acute kidney injury (AKI) is common among hospitalized patients, occurring regardless of the admitting specialty, but more frequently in critically ill individuals. It develops secondary to multiple conditions, nephrotoxic agents, or the cumulative effect of small renal insults. Its incidence has been increasing and is expected to continue rising, largely due to invasive interventions and comorbidities in older adults.
There is no specific treatment; conventional management is limited to treating complications resulting from impaired kidney function. Infections occur in up to 40% of patients as a consequence of immune suppression associated with this syndrome.
This study aims to prevent such infections during the first 3 months after hospital discharge for AKI through the administration of trimethoprim/sulfamethoxazole (TMP/SMX) 800/160 mg every 48 hours for 3 months, with the goal of reducing infections and hospitalizations.

What will I have to do to participate?
To determine whether you are eligible for this study, you will provide a medical history and undergo a thorough physical examination. You will provide urine and blood samples (approximately 2 teaspoons) for a complete blood count, kidney and liver function tests, and measurement of inflammatory markers; these evaluations will take place during your hospitalization and at 28, 60, and 90 days after enrollment.
You will be randomized to either receive conventional management per international guidelines plus TMP/SMX tablets to be taken for 3 months, or to receive standard care alone.
After initiation of the assigned treatment, study visits will occur daily during hospitalization and at 28, 60, and 90 days after enrollment. During these visits, nephrology specialists (the study team) will examine you, obtain vital signs, perform physical examinations, review laboratory results, and discuss any symptoms, discomfort, or additional medications taken.

What are the risks and discomforts?
In previous studies, TMP/SMX has generally been well tolerated (participants experienced few side effects). The most commonly reported side effects include skin rash, hypersensitivity reactions, and gastrointestinal discomfort. Fatigue has been reported in a small number of participants. Dermatosis (rash) has also been reported, usually after sun exposure (photosensitivity), as well as elevations in serum potassium and serum creatinine. A small percentage (5–10%) of individuals who developed dermatosis experienced symptoms severe enough to discontinue the study drug. In all cases, the dermatosis resolved after discontinuation. The likelihood of anaphylaxis is very rare (0.6%) in recent studies.
Blood sampling of approximately 10 mL (2 teaspoons), performed for the measurements required by this protocol, carries additional risks, including discomfort associated with needle insertion, infection, bruising, temporary irritation, or discoloration at the puncture site. Fainting during blood collection is rare. You should carefully review all these risks with any of the physicians participating in the study.

You must contact your treating physician immediately if, during the course of the study, any of these (or other new) side effects develop. If your physician informs you that your condition has worsened, or that side effects may become more severe, or if new scientific developments suggest that this treatment is no longer appropriate for you, your participation will be discontinued.
In the event of death, a post-mortem examination (autopsy) may be considered. If you agree, it may be performed under your current authorization, and your decision will also be discussed with your family

Are there alternative treatments?
Your alternative is not to participate in this study. Your doctor can provide you with detailed information regarding your current treatment and the benefits of the various therapeutic options available to you. You have been informed that you are free to discuss these alternatives (and the prognosis of your condition), as well as other available options, with your physician.
Standard care for acute kidney injury commonly includes treatment with furosemide, antihypertensive medications, bicarbonate, among others. You may receive any of these treatments during this trial. If new information regarding side effects becomes available during the course of the study, it will be made available to you.

Will my identity and medical information be kept confidential?
Your identity in this study will be kept confidential, and any information obtained about you during the course of the study will remain confidential. When recording protocol results, you will be identified only by a code number and initials. All information regarding your participation in this research will be available to the study personnel, the Ethics Committee of Hospital Civil de Guadalajara Fray Antonio Alcalde, the University Center for Health Sciences of the University of Guadalajara, COFEPRIS, the Mexican Ministry of Health, and any other appropriate health authority.

Disclosure of medical information to any other parties will require your authorization, except in response to a judicial subpoena or as otherwise permitted by law.

What are the benefits of participating?
You may not receive direct benefit from your participation in this study. However, although you may not personally benefit, the knowledge gained from this research may benefit society as a whole. Any information obtained in this study that may be important for your health or disease progression will be shared with you. In addition, we will gather knowledge regarding improvement in clinical symptoms and signs, as well as in biochemical parameters during patient follow-up.

Will I be compensated for participating?
You will not be charged for the study drug. All costs related to the routine treatment of kidney disease or other medical conditions—including emergencies, hospitalizations, and tests not specified in the study protocol—are your responsibility. If you are a patient at Hospital Civil

de Guadalajara, you will continue to receive routine care in accordance with institutional guidelines.
You are responsible for the cost of any medication (other than TMP/SMX) prescribed for the management of your disease or concomitant conditions during your participation in this study.

Insurance and Financial Compensation
In the event of adverse events attributed to the study drug, the investigators will not pay for the treatment of medical complications that are part of the natural course of your primary disease, nor will they provide any other form of compensation to any participant.
The medical care you receive will not change in any way, regardless of your original condition as a patient with kidney disease. You are covered by Hospital Civil de Guadalajara and will receive the best medical care possible if you experience an adverse event as a result of the study drug. You will not be paid for your participation in this study.

Whom should I contact if I have questions about my rights as a research participant?
If you have any questions about this research, or if you experience any study-related injury, please contact the Principal Investigator:
Jonathan Samuel Chávez Iñiguez, MD, Nephrology Specialist
Mobile: +52 33-1329-9609
Landline: +52 (33) 3942-4400, extensions 49312 and 49272
Hospital Civil de Guadalajara, Department of Nephrology.

If you have questions regarding your rights as a research participant, you may contact the Ethics Committee of Hospital Civil Fray Antonio Alcalde, University of Guadalajara, which is committed to protecting individuals participating in research studies.

Will I be notified of important new findings?
As the research progresses, any important new information that may be relevant or beneficial to you will be communicated and explained to you, insofar as it relates to your treatment.

What are your rights as a participant in this research?
You voluntarily consent to participate in this clinical research study. You have been informed of what your participation entails, including possible risks and benefits.
Your participation may be discontinued by your physician without your consent for the following reasons:

1. Worsening of your health or other conditions that could be harmful if you continue;
2. Failure to attend follow-up visits or to take the study medication as indicated;
3. Receiving treatment with medications for acute kidney injury or chronic kidney disease that are not accepted by the study team;
4. A serious adverse event (side effect) related to the study drug;
5. Kidney transplantation;

6. Becoming HIV-seropositive;
7. Termination or suspension of the study by the sponsor.

You may also be withdrawn from the study at any time at the discretion of the study physician for any reason deemed appropriate.

You may refuse to participate or withdraw your consent, or discontinue your participation at any time without penalty and without affecting your future care or your ability to receive alternative medical treatment at any of the Civil Hospitals of the University of Guadalajara. If you withdraw from the protocol, you may seek treatment from another physician of your choice.

If you choose to withdraw, the investigator will request your permission to continue monitoring your case. All clinical data relevant to the research will continue to be recorded in your medical file.

Statement of Irrevocable Legal Rights

By agreeing to participate in this study and by signing this informed consent form, you are not waiving any of your legal rights.

You affirm that you have read this informed consent form. You have been informed that you will receive a copy.

Signatures

_____	_____	_____
Printed Name of Patient	Signature	Date

_____	_____	_____
Printed Name of Legal Representative	Signature	Date

_____	_____	_____
Printed Name of Witness I	Signature	Date

_____	_____	_____
Full Address of Witness I	Relationship to Patient	

_____	_____	_____
Printed Name of Witness II	Signature	Date

_____	_____	_____
Full Address of Witness II	Relationship to Patient	

_____	_____	_____
Printed Name of Principal Investigator or of the person conducting consent	Signature	Date