INFORMED CONSENT FORM FOR CLINICAL TRIALS WITH INVESTIGATIONAL MEDICINAL PRODUCTS IN ADULT PATIENTS

Study on the effect of reduced salt administration via intravenous fluids in critically ill adults in Intensive Care.

Official study title: Effect of Reduced Sodium Chloride in Fluid Creep and Maintenance Fluids in Critically Ill Adults: A Randomized Controlled Trial

EU number: 2025-520744-14-00 NCT number pending
Study number: 003813
Sponsor: University Hospital Antwerp

Study Center Name: *Ziekenhuis aan de Stroom (ZAS)* *Universitair Ziekenhuis Antwerpen (UZA)*

Study Center Address: *Kempenstraat 100 – 2030 Antwerp* *Drie Eikenstraat 655 – 2650 Edegem*

Study Center Number: *009* *300*

Overview of changes to the document

Version nr.	**Publication date**	**Description of adaptations**
1.0	08 MAR 2025	First version, with modifications based on the advice of a patient representative.

Who to contact in case of questions

Name	**Function**	**For**	**Contact details**
***	Principal Investigator	Information, concerns, problems	***
	Study staff	Information, concerns, problems	***
	Urgent study queries	24/7 Urgent information,	***

		concerns, problems	
Amma Kunstlaan 39/1 1040 Brussel	Insurance company of the Sponsor	Claims or disputes regarding harm	***
	Data Protection Officer	Questions regarding data confidentialit	***
	Belgian Data Protection Authority	Complaints regarding data confidentiality	***

***** RESEARCH PARTICIPANT INFORMATION REMOVED AS PER CLINICALTRIALS.GOV INSTRUCTIONS *****

If any issues arise that cannot be resolved by the study investigator, you may contact the study center's ombudsman at the address above.

- *According to GDPR, you have the right to access and review your data processing.*
- *For any inquiries, contact the Data Protection Officer at the above address. You also have the right to file a complaint with the Belgian supervisory authority for data protection compliance*, see above

Version number: *1.0*

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STUDY OVERVIEW

Why are you being asked to participate in this study?
You are being asked to participate in this study because you are admitted to the Intensive Care Unit (ICU) and require treatment with intravenous fluids. The study investigates whether limiting the amount of sodium chloride in commonly used intravenous fluids and medication diluents has a beneficial impact on your health and recovery.

What is the purpose of the study?
The study aims to assess whether reducing sodium chloride in intravenous fluids for ICU patients positively affects their health and recovery. This is done by adjusting the sodium levels in maintenance fluids and medication diluents. Maintenance fluids provide water and electrolytes to patients who cannot eat or drink. Some intravenous fluids contain more sodium than others, and we want to investigate whether a modified composition improves recovery and health outcomes in ICU patients.

Will you benefit from this study?
It is uncertain whether you will personally benefit from this study. However, the results may contribute to improved treatments for future patients.

What does the study treatment involve?
Two different procedures will be compared:

1. One group of patients will receive medication dissolved in **5% glucose (sugar water)** and, when necessary, maintenance fluid with a small amount of sugar and low sodium.
2. The other group will receive medication dissolved in **normal saline (NaCl 0.9%)**, and their maintenance fluid will be **PlasmaLyte**, which contains electrolytes similar to human blood but no sugar.

Your fluid regimen will be determined randomly (by lottery). All these fluids have been safely used in hospitals for years. You will continue to receive your standard medical treatments.

What tests will be conducted?
Your ICU treatment will continue as usual. No extra blood samples will be taken for the study. Instead, data will be collected from routine tests, and one additional test measuring **urea levels** (a waste product excreted by the kidneys) will be performed on routine blood samples.

How long does the study last?
Your participation will continue as long as you need intravenous fluids during your ICU stay, which can range from several days to weeks. Once discharged from the

ICU, the study procedures will stop, and you will receive standard fluid management. The study team will follow up with you **90 days after ICU admission**.

Are there any side effects?
The intravenous fluids used in this study are standard hospital treatments and are considered safe. No new drugs are being tested. However, as with any treatment, side effects may occur, such as **fluid retention, electrolyte imbalances (sodium or glucose disturbances), or kidney issues**. These risks are monitored as part of routine ICU care.

Is there insurance if something goes wrong?
Yes, the study is insured. If unexpected harm or side effects occur due to participation, the insurance will cover any related costs.

Who is paying for the study? Do I have to pay anything?
The study is fully funded by the researchers. **You will not have to pay for any study-related treatments.**

Will my data be kept confidential?
Yes. Your data will be anonymized and used solely for scientific research. Only authorized study personnel and regulatory bodies may review your data.

Do I have to participate?
No. Participation is **completely voluntary**. You can withdraw at any time without affecting your medical care. If you withdraw, your routine treatment will continue, but the study will no longer determine which fluids you receive.

Who has approved this study?
The study has been reviewed and approved by an independent **Medical Ethics Committee** and the **regulatory authorities** to ensure it meets ethical and safety standards.

Can I continue using the study fluids after the trial?
The fluids used in the study are standard hospital products. Your doctor will revert to the hospital's standard treatment after your participation ends.

CHAPTER I - DESCRIPTION OF THE STUDY AND YOUR RIGHTS DURING PARTICIPATION

1. What is the purpose of the study?

The purpose of this study is to investigate whether **reducing the amount of sodium chloride in intravenous fluids impacts patient recovery.** Some studies suggest that excessive sodium intake may have negative effects, such as fluid retention, kidney problems, increased need for ventilation or dialysis, or prolonged ICU stays. Conversely, alternative solutions may contain too little sodium and always a small amount of sugar, which could cause other issues, such as high blood sugar or low sodium levels.

All fluids used in this study have been safely used in hospitals worldwide for years and are standard treatments. The key difference between these fluids is their sodium and chloride content. In this study, researchers will attempt to minimize sodium intake in one half of the patients, while the other half will receive a sodium amount commonly used in many hospitals. It is important to note that the amount of fluids you receive will not be determined by the study but by your physician. The study only determines the composition of the fluids. Any side effects, including sodium and sugar imbalances, will be closely monitored and treated in the ICU.

This research aims to determine whether a fluid management strategy with lower sodium content improves recovery in ICU patients. Additionally, the study will assess differences in side effects, hospital length of stay, and the impact on patient survival.

A total of **640 patients** will participate in this study, conducted across multiple hospitals in Belgium. All participants will be randomly assigned to one of two fluid management groups.

By participating in this study, you help us develop better treatments for future patients. **Your standard medical treatment will not change.** The intravenous fluids used in this study are not new—they have been routinely used in hospitals for a long time.

2. Why am I being asked to participate in this study?

You are being asked to participate in this study because you have been diagnosed with **a condition requiring intravenous fluids during your stay in the Intensive Care Unit** (ICU). The doctors aim to investigate whether administering fluids with reduced sodium chloride impacts your recovery and whether this treatment causes any side effects.

You qualify for this study because:

- You are admitted to the ICU and receiving intravenous fluids.
- You meet the medical criteria for the study. Preliminary checks have been conducted to ensure that the fluids used in the study will not be harmful to your specific condition.

The researcher or study personnel will discuss the eligibility criteria with you. If you are too ill to provide consent at the time, this discussion will first take place with a legal representative (e.g., a close family member), or an independent physician will decide on your inclusion.

If you choose not to participate, you will receive the standard intravenous fluids typically used in this hospital for both maintenance fluids and medication dilution.

It is not certain that your participation in this study will cure your condition, improve your quality of life, or prolong your life

3. Do I have to participate in this study?

Participation in this study is entirely voluntary and should never be done under pressure. You have the right to decline participation. You may also withdraw at any time without providing a reason, even if you previously agreed to participate. Your decision will not affect your relationship with the researcher or your treating physician, nor will it impact the quality of your future medical care.

4. What will happen during the study?

Approximately 640 participants in Belgium will be involved in this study.

This is a randomized study, meaning that the type of intravenous fluid you receive will be assigned at random (by lottery). This process ensures the study results are as fair and reliable as possible. Neither you nor the ICU team (doctors and nurses) will know in advance which fluid you will receive (double-blind study).

4.1. Study phases:

- Screening:
    - Your physician will assess whether you qualify for the study.
    - You will receive an explanation and have the opportunity to ask questions before deciding whether to participate.
    - If you are too ill to participate in this discussion, a legal representative (e.g., a close family member) or an independent physician may provide consent, allowing treatment to start immediately without prior approval. This is called **deferred consent**. Deferred consent has been approved by the Ethics Committee and government authorities for this study because all potential side effects are closely monitored in the ICU and because the study is considered important for medical advancement. As soon as you or your representative can make an informed decision, the researcher will explain the study and seek consent for continued participation. You or your representative may withdraw from the study at any time.
- Treatment Phase:
    - You will be randomly assigned to one of two intravenous fluid groups (one with lower sodium levels and one with standard sodium levels). This is called randomization.
    - The treatment will start as soon as possible after assignment.
    - Throughout your ICU stay, standard medical assessments will be conducted, including blood tests and fluid balance monitoring. No extra blood samples will be taken specifically for the study, but one additional test (urea levels) will be performed on routine blood samples every two days.

- Follow-Up Phase:
    - Your recovery and any potential side effects will be monitored as long as you remain in the ICU.
    - Approximately 90 days after your ICU admission, we will contact you for additional follow-up questions.

4.2. How long will I be in the study?

Your treatment with the assigned intravenous fluids will last as long as you remain in the ICU. This could range from several days to weeks, depending on your medical condition. The study follow-up will conclude **90 days after your ICU admission**.

4.3. What do I need to do as a participant?

You will receive the assigned fluid regimen according to the study guidelines.

- You will undergo standard medical assessments as part of your ICU care.
- You should report any symptoms or side effects to your physician.

4.4. Will I have to pay for anything?

- The study is fully funded, and you will not have to pay for any study-related treatments.
- Standard medical treatments that are not part of the study will be covered as usual by your health insurance.

By participating, you are helping us determine the best fluid management strategy for ICU patients.

5. Will I benefit from this study?

The information collected may contribute to better understanding fluid management in critically ill patients and help develop improved treatment strategies for you or future patients.

The fluid strategy being studied may or may not be beneficial for your ICU treatment. Even if it proves beneficial, there is still a possibility of symptom recurrence or worsening. All potential side effects will be closely monitored in the ICU and treated if necessary.

6. What are the possible risks and discomforts of participating in the Study

6.1. What are the potential side effects of the intravenous fluids?

Participating in a study involves some level of risk. Both fluid management strategies in this study may have potential side effects. Since these fluids have been used in hospitals for a long time, most of their effects are well known, but absolute certainty cannot be guaranteed.

Previous studies have shown that reducing sodium intake by using low-sodium fluids (such as glucose 5% or NaCl 0.3% dissolved in glucose 5%) is generally well tolerated. However, potential side effects include:

- **Decreased sodium levels in the blood**, which, in severe cases, may cause consciousness disturbances. This is very rare and is closely monitored in the ICU.
- **Elevated blood sugar levels**, which is common in ICU settings and usually results from the body's response to illness, trauma, or surgery. Blood sugar levels are routinely monitored multiple times a day and managed with insulin if necessary.

Studies have also shown that commonly used solutions such as normal saline (NaCl 0.9%) and PlasmaLyte (which contain higher sodium levels) are generally well tolerated. However, potential side effects include:

- **Fluid retention**, which may require additional support such as prolonged mechanical ventilation or dialysis. This is common in ICU patients and is usually caused by the body’s response to illness, trauma, or surgery. Fluid balance is closely monitored in the ICU and managed with diuretics if needed.
- **Increased sodium levels in the blood**, which, in rare cases, can lead to consciousness disturbances. This is continuously monitored in the ICU.
- **Increased chloride levels in the blood**, which may increase the risk of kidney failure or the need for dialysis. This is frequently observed after fluid treatment or in patients with pre-existing kidney issues and is regularly monitored in the ICU.
- **Decreased blood sugar levels**, which is also routinely monitored in the ICU and managed with insulin if necessary.

The exact frequency of these side effects specifically caused by ICU fluid management is not yet known. Determining this information is one of the objectives of the study.

Both treatment approaches may also carry the risk of **prolonged ICU or hospital stay**. The study also aims to determine whether these treatments affect **patient survival rates**.

Since this fluid strategy is still under investigation, there is a possibility of additional, currently unknown risks or discomforts. Therefore, it is essential that you **immediately report any new or worsening health issues to the study investigator**, even if you believe they are unrelated to the study or have already been described in this document.

6.2. What are the possible risks or discomforts associated with study assessments?

All assessments conducted in this study are part of routine ICU care, meaning no additional risks are involved. One extra test (urea levels) will be performed on a blood sample that is already being collected as part of standard care.

6.3. Can I take other medications during the study?

Other medications are **not restricted** during this study.

7. What happens if something goes wrong during the study?

Even if no error occurs, the **Sponsor** (University Hospital Antwerp) is liable for any harm you may suffer that is directly or indirectly related to your participation in this clinical study. The sponsor has taken out an appropriate **no-fault insurance policy**, in accordance with current European and Belgian legislation on clinical trials. A copy of the insurance certificate is available from the investigator or study staff.

If you (or, in the case of death, your legal beneficiaries) wish to claim compensation for health-related harm directly or indirectly caused by participation in the clinical study, you must notify the study staff immediately.

If the investigator believes there may be a link between any new or worsening health problems and the clinical study, they will inform the study sponsor. The sponsor will then initiate the insurance claim process with its insurer. If deemed necessary, the insurer may appoint an expert to assess whether there is a connection between your reported health issues and the clinical study. The insurance **does not cover** the natural progression of your illness or known side effects of treatments that you would have received as part of your standard care outside the clinical study.

If you or your legal beneficiaries disagree with the investigator or the expert appointed by the insurance company, you may contact the insurer directly or initiate legal proceedings against the insurance company. The contact details for the insurer are provided on the cover page of this form.

8. What happens if new treatments or important information about the intravenous fluids become available during the study?

During the course of the study, new significant information may become available that could influence your decision to continue participating. For example, other treatments or crucial new data about the fluids being used may emerge. It is the investigator’s responsibility to discuss this new information with you and provide you with the opportunity to reconsider your participation in the study.

If you decide to withdraw from the study or if you are no longer eligible to continue, the investigator will ensure that you receive the best possible standard treatment

9. Can my participation in the study end early?

As discussed in further detail in this section, your participation in the study may end early in the following cases:

1. You decide to withdraw your consent for both the study treatment and the collection of routine data.
2. You decide to stop only the study treatment but allow continued collection of routine data.
3. The researcher decides to end your participation in the study.
4. Other entities interrupt or terminate the study.

If your participation in the study ends early, the researcher will discuss with you what follow-up medical care will be provided. The data collected before your withdrawal will still be used, as described in this document, to avoid misinterpretation of the study results (as described in section I.§ 12.4).

Depending on your situation, the researcher will determine whether follow-up visits or procedures are necessary.

If, after withdrawing from the study, you experience a new side effect, you may still contact the researcher for follow-up.

9.1. You decide to withdraw your consent for the study treatment and the collection of routine data

You may decide to withdraw your consent at any time without giving a reason. However, for your own safety, you should inform the researcher of your decision.

Even though it is not required, it may be helpful for the researcher and the study sponsor to understand your reason for withdrawing (e.g., side effects).

If you withdraw your consent, this means that you decide to stop:

- Receiving the study-assigned IV fluid treatment.
- All study-related procedures and tests.

No further data will be collected or sent to the study sponsor. If your legal representative or doctor enrolled you in the study without your explicit consent, you may also request that your previously collected data be deleted.

However, if biological samples (e.g., blood samples, urine samples) have already been used or analyzed before you withdrew consent, the study sponsor still has the right to use the results of those tests.

9.2. You decide to stop only the study treatment but allow continued collection of routine data

It is possible to stop receiving the study-assigned IV fluid treatment but still agree to continue providing data and allow contact with the study team.

If you decide to stop the study treatment, the study staff may ask for permission to:

- Contact you by phone, email, or post approximately three months after your ICU admission to ask about your general health.
- Access your medical records in public health databases until the end of the study.

This information is important for the scientific validity of the study and helps ensure accurate interpretation of the results.

However, you are free to refuse contact. Your decision will not affect your future medical care.

9.3. The researcher decides to end your participation in the study

The researcher may decide to withdraw you from the study if:

- They believe it is in your best interest (e.g., based on your test results or if you develop health complications).
- You do not follow the study protocol.
- There is another reason, which will be explained to you.
- The entire study is discontinued for all participants.

If this happens, the study staff will explain why and will ensure that you receive appropriate medical follow-up.

9.4. Other entities may interrupt or terminate the study

The study sponsor and regulatory health authorities may decide to suspend or stop the study if:

- The collected data suggests that the study treatment is less effective or more harmful than expected.
- The study treatment causes more (or more severe) side effects than anticipated.
- For any other justified reason, which will be explained to you.

10. What treatment will I receive after participating in the study?

After you have completed the study treatment, the investigator will assess your health status. If necessary, they will prescribe the best available standard treatment or refer you to another physician of your choice.

If you have completed the entire study, the investigator may invite you to participate in a follow-up study where additional data will be collected that were not included in the current study. The investigator will propose this option if they believe it may be beneficial for you and if you meet the inclusion criteria for the follow-up study. Participation in any future follow-up study is entirely voluntary.

11. Will my participation in the study result in additional costs for me?

11.1. Tests and treatments covered by the sponsor

As described in Section 4, the tests and treatments performed specifically for the study will not be charged to you. Any treatments and tests that are part of your standard medical care will be billed to you or your health insurance provider.

In other words, the sponsor will reimburse the hospital or study center for:

- The time spent by the investigator and study staff on the study.
- The visits/consultations and all planned tests specifically related to the study.
- The studied treatment (fluid management strategy), any additional medication, and other materials used specifically for the study.

11.2. Will I receive compensation for participating in the study, or can I claim expenses?

You will **not** receive financial compensation for participating in this study, and there are no additional costs that you can claim reimbursement for through the study.

12. What data will be collected about me during the study and what will happen to it?

12.1. Which data will be collected and processed during the study?

The collected and processed personal data concern your health and medical condition, including your medical history, some background information (such as your age, gender, and ethnic origin), and the results of study-related tests.

Information about your ethnicity is collected only because the amount of salt typically consumed (outside the hospital) varies by ethnicity. Some cultures consume more or less salt than others. The way the body processes salt through IV fluids in the hospital is influenced by the usual dietary intake of salt.

This data is collected to ensure that the study results apply to as broad a population as possible. The data will be stored in an electronic database called REDCap.

12.2. How will the researcher handle my personal data?

The researcher (and study staff) is bound by medical confidentiality when collecting and processing your data.

This means that **your identity will never be disclosed**, including in scientific publications or presentations. The researcher will **code your data** (i.e., replace your identity with an identification code) before sending it to the study sponsor.

This code will not contain any personally identifiable details, such as your name, initials, full or partial date of birth, or patient record number.

As a result, only the researcher and study staff, under the researcher's responsibility, will be able to link your identity to the study data, except in the cases described under § 12.5.

If your data is processed in the electronic database REDCap, only the identification code will be used—no personally identifiable data will be stored. The data received by the sponsor will not allow them to identify you.

12.3. How will my data be processed?

Your study data will be processed in compliance with the current European and Belgian data protection laws.

The reason your personal data may be processed for the study is that it is used for scientific research, and that you, your legal representative, or an independent physician has provided consent (see the section on deferred consent under § 4).

12.4. Do I have access to my data collected and processed during the study, and can I correct it?

You have the right to ask the researcher which data about you has been collected and how it is used in the study.

You have the right to:

- Access your data and review it
- Have your data deleted if you withdraw consent that was initially provided by a legal representative or an independent physician
- Receive a copy of the personal data collected
- Request correction of any incorrect information
- Withdraw your consent for data processing

However, any data collected before your withdrawal will be retained to avoid misinterpretation of the study results.

It is not possible to:

- Request full deletion of your data once you have provided written consent
- Restrict the processing of your data
- Object to the processing of your data

These restrictions are in place to ensure the study results are not misinterpreted.

12.5. Who, other than the researcher and their staff, has access to my personal data?

To ensure the quality of the study, your non-coded personal data or relevant medical records may be inspected by individuals other than the study staff. This inspection takes place under the supervision of the researcher. These individuals are bound by medical confidentiality or a confidentiality agreement. This may include:

- Study monitors and auditors appointed by the study sponsor, as well as individuals or organizations that provide services to or collaborate with the sponsor. However, they will never share your name or contact details with the sponsor.
- Inspectors from the regulatory health authorities worldwide.
- An independent audit group.
- Individuals designated by the Ethics Committee.

If necessary for the study, coded (anonymized) data may be transferred to other countries inside and outside the European Union (EU) and reviewed by:

- Health authority personnel (other than inspectors) from Belgium (Federal Agency for Medicines and Health Products, FAGG) or other countries inside and outside the EU
- Belgian Ethics Committees
- External researchers
- The study sponsor, sponsor-appointed personnel, and organizations providing services to or collaborating with the sponsor
- Other companies within the sponsor's group, both in Belgium and in other EU and non-EU countries

European and Belgian data protection laws impose restrictions on the transfer of data to non-EU countries. The study sponsor must always ensure that your coded study data is protected to the same standard when transferred outside the EU.

If the study sponsor enters into a data protection agreement for this purpose, a copy of the agreement can be obtained from the researcher.

You may contact the researcher at any time for more information about such data transfers.

12.6. What will happen to the results of the study?

After the study is completed, a description and results of the study will be published in specialized medical journals. A copy of the scientific publication can be obtained from the researcher or study staff. A summary of the study results will also be available on https://euclinicaltrials.eu/search-for-clinical-trials/?lang=nl.

Using the information provided in this document, you can look up the study on this website. Within one year after the study is completed, the website will contain a summary of the results in accordance with European Commission guidelines.

The website and publications will not contain any information that can identify you. A description of this clinical study is also available at https://www.ClinicalTrials.gov, as required by U.S. law. This website does not contain any information that could identify you, but it may include a summary of the study results.

You may visit this website at any time.

12.7. Will my data be used for purposes other than the study I am participating in?

The results of the study will be used to answer the scientific questions specific to this study. Additionally, the study sponsor may wish to use your data in other research and development activities (including related scientific publications). These activities must be related to the effect of sodium intake on ICU patients. Any additional or future research outside this study, which is not described above, must first be approved by a recognized Belgian Ethics Committee.

12.8. How long will my data be retained?

After the study is completed, your coded data will be stored for at least 25 years, in accordance with European clinical trial regulations. This ensures the validity of the research.This retention period applies even if you withdraw early from the study.

13. Which biological samples will be collected from me during the study, and what will happen to them?

No biological samples will be collected outside the routine treatment in Intensive Care.

14. What if the research reveals significant information about your health?

During the study, it is possible that we discover new information about your health. If this information could be relevant to your well-being, the study sponsor will notify the researcher. With your permission, the researcher will inform you and your treating physician about the results and their potential consequences. If necessary, the researcher and/or your treating physician will provide guidance on the appropriate next steps.

15. Who has reviewed and approved the study documents?

The study documents have been reviewed by:

- The **Belgian regulatory health authorities (FAGG)** or, where applicable, the national regulatory authorities of other EU member states.
- An **independent Belgian Ethics Committee.**

The regulatory authorities and Ethics Committees are responsible for protecting individuals participating in a study. They ensure that the study is conducted in accordance with applicable laws and ethical guidelines.

Their approval should not be interpreted as an encouragement to participate in the study

CHAPTER II – INFORMED CONSENT

Study on the effect of reduced salt administration via intravenous fluids in critically ill adults in Intensive Care.

PARTICIPANT

PREREQUISITES FOR YOUR PARTICIPATION IN THE TRIAL

- I declare that I have been informed of and that I understand the purpose of the clinical trial, its duration, possible risks and discomforts, the precautions that I have to take and what is expected of me. My rights have been explained to me and I have understood those rights.
- I have had enough time to think about taking part in this trial and to discuss it with a trusted person (for example friends, relatives, treating physician, …).
- I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.
- I understand that my participation in this trial is voluntarily and free from any coercion and that I am free to stop at any time my trial participation.
- I understand that data about me will be collected and that they will be treated confidentially.
- I agree to my personal data being processed as described in Chapter I, § 12.
- I understand that the sponsor has taken out an insurance in case I should suffer any damage in connection with my participation in this trial.
- I understand that when participating in this trial, I will not have any costs except those related to the standard of care treatment of my disease
- I agree to my treating physician(s) being informed of my participation in this trial.
- I agree not to take part in any other trial at the same time without first informing the investigator or the trial staff, who might not permit me to participate for a good reason.
- I understand that I need to cooperate and follow the investigator's and trial staff's instructions regarding the trial.
- I understand that participation to the trial might end for me without my consent if I need other treatment, do not follow the trial plan, have a trial-related injury, or for any other justified reason.
- I am aware that the results of the analysis of any anonymized biologicals samples and the possible remainders of samples will not be available for me (Chapter I, § 13.2, page **Fout! Bladwijzer niet gedefinieerd.**).

- I certify that all the information I have given about my medical history is correct. I understand that my failure to inform the investigator or designee about any exclusion criteria may harm myself.

I consent to take part in the trial and I have received a signed and dated copy of all pages of this document.

Participant's surname and first name:

Date (DD/MMM/YYYY):

Participant's signature:

LEGAL REPRESENTATIVE OR TREATING PHYSICIAN (REF. [1])

I declare that I have been informed that I am being asked to take a decision on whether or not to take part in the clinical trial for the person I represent, considering his/her best interests and taking into consideration his/her likely wishes. My consent applies to all the items listed in the consent of the participant.

I have also been informed that as soon as the clinical situation allows, the person I represent will be made aware of his/her participation in a clinical trial and from that point will be free to continue with this participation or end it by signing or refusing to sign this consent form.

I have received a signed and dated copy of this document.

<table>
<tr><td>Legal representative’s surname and first name</td><td rowspan="2">Treating physician’s surname and first name</td></tr>
<tr><td>Relationship to the participant:</td></tr>
<tr><td>Date (DD/MM/JJJJ)</td><td>Date (DD/MM/JJJJ)</td></tr>
<tr><td>Time:</td><td>Time:</td></tr>
<tr><td>Legal representative’s signature:</td><td>Treating physician’s signature:</td></tr>
</table>

IMPARTIAL WITNESS / INTERPRETER (REF.[2])

I, the undersigned (Tick as appropriate),

☐ Impartial Witness

☐ Interpreter

was present during the entire process of informing the participant and I confirm that the information on the objectives and procedures of the trial was adequately provided, that the participant (or his/her legal representative) apparently understood the trial and that consent to participate in the trial was freely given.

I declare furthermore that acting as an impartial witness, I am independent of the sponsor and the investigator.

Impartial Witness / Interpreter surname and first name:

Impartial Witness / Interpreter qualification:

Date (DD/MMM/YYYY):

Impartial Witness / Interpreter signature:

INVESTIGATOR

- I, the undersigned investigator, confirm that
- the participant has been verbally provided with the necessary information about the trial, has been explained the content and has been given an original signed document.
- I have verified that the participant has understood the trial.
- I have given the participant sufficient time to agree to take part and to ask any questions.
- no pressure was applied to persuade the participant to agree to take part in the trial.
- I operate in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, the “Good Clinical Practices” and the Belgian Law of 7 May 2017 on clinical trials with medicinal products for human use.

OPTIONAL SIGNATURE BY A DELEGATE	MANDATORY SIGNATURE BY THE INVESTIGATOR
Investigator’s delegate, surname and first name, qualification:	Investigator, surname and first name:
Date (DD/MM/JJJJ)	Date (DD/MM/JJJJ):
Time:	Time:
Investigator’s delegate signature:	Investigator’s signature

GLOSSARY OF TERMS

DPA: The Data Protection Authority ensures that personal data are handled with care and thoroughly protected, and that your future privacy also remains guaranteed.

FAMHP: Federal agency for medicines and health products

IMP: investigational medical product

No Fault insurance: The sponsor is liable for any injury or any damage that the participant has suffered, and which is directly or indirectly related to the clinical trial. You do not have to prove any mistake in this respect.

MONITOR and AUDITOR: Both the monitor and auditor work for the sponsor. The monitor takes care of a continuous quality check during the course of a trial. The auditor performs a quality check after the trial. They verify if the trial is being/was conducted according to the protocol, if the reported data are liable and if the clinical trial was conducted according the applicable rules

FLUID MANAGEMENT: Doctors prescribe intravenous (IV) fluids to patients for various reasons: to provide sufficient water and salt, to treat shock, or to replace lost fluids (e.g., due to diarrhea, fever, or sweating). The amount, speed, and type of fluid prescribed are collectively referred to as "fluid management."

NACL: This is simply table salt. The individual components, sodium and chloride, are the primary ions in human blood. IV fluids therefore almost always contain some amount of sodium and chloride. Normal saline (NaCl 0.9%) contains 0.9g of NaCl per 100 mL. For comparison, a healthy diet typically contains only 5 to 6g of NaCl per day.

PLASMALYTE: A specific IV fluid that is commonly prescribed. It contains approximately the same amount of NaCl as human blood.

GLUCOSE 5%: A solution containing glucose at a concentration of 5g per 100 mL. It does not contain salt and can therefore be excreted by the kidneys more easily.

REFERENCES

[1] When an adult is unable to express their will, a legal representative must be appointed, following a sequential order: the person previously designated by the patient to act on their behalf, a court-appointed guardian, or, in the absence of these, the cohabiting spouse, legally cohabiting partner, de facto cohabiting partner, adult child, a parent, or an adult sibling.

If the person authorized under the second paragraph is unwilling or unavailable, the responsible healthcare professional will safeguard the patient's interests, where applicable, through multidisciplinary consultation.

This regulation is established in Article 11 of the Law of May 7, 2017, on experiments involving human subjects, and in Articles 12 and 14 of the Law of August 22, 2002, on patient rights.

In this study, a treating physician who is not acting as a researcher for the study may grant consent for the patient's participation while awaiting the appointment of a legal representative, or in the absence of one, as long as the patient is incapable of giving consent themselves.

[2] Use of an impartial witness is necessary when either the subject or the subject's legally authorized representative speaks and/or fully understands the language of the approved informed consent form, but cannot read and write due to any physical impairment or is visually impaired. An interpreter is necessary when the investigator doesn't speak the language of the patient