Dear Parent,

Title of the Study:

Eficacy and Safety of Restricted Fluid Therapy in Transient Tachypnea of the Newborn: A Randomized Controlled Study

Purpose of the Study:

This study concerns transient tachypnea of the newborn (TTN), which is the most common cause of respiratory distress in term or near-term infants. Before birth, the lungs of the fetus are filled with a fluid called fetal lung fluid. This fluid is essential for lung development during intrauterine life. When labor begins, this fluid starts to be cleared from the lungs. After birth, with the first breaths, the remaining fluid is removed and the lungs fill with air. A delay in the clearance of this fluid may lead to respiratory distress in the newborn (rapid breathing, grunting, chest retractions, and cyanosis), known as transient tachypnea of the newborn.

In most infants, this fluid is gradually cleared within 2–4 days, and breathing returns to normal. However, in some infants, the condition may be more severe and prolonged.

Your baby shows clinical findings consistent with transient tachypnea of the newborn. In addition, chest X-ray findings also support this diagnosis.

All infants admitted to the neonatal unit due to respiratory distress are closely monitored for respiratory rate, heart rate, blood pressure, blood glucose levels (measured three times daily initially), blood gas analysis, urine output, and daily body weight. Most of these infants require respiratory support (such as oxygen, nasal continuous positive airway pressure, or mechanical ventilation). After the first 24 hours of life, liver and kidney function tests, as well as serum sodium, potassium, chloride, and calcium levels, are evaluated. Blood glucose and blood gases are monitored periodically. Infants with more severe disease are followed more closely.

Since your baby has respiratory distress, he/she will be monitored accordingly.

The treatment of transient tachypnea of the newborn is mainly supportive and includes providing respiratory support, withholding oral feeding if respiratory rate is very high or feeding via a nasogastric tube in small amounts, and meeting fluid and nutritional requirements intravenously. Various medications have been tried to prevent disease progression and accelerate recovery; however, studies have shown that these treatments do not shorten the duration of the disease. Therefore, currently, no specific medication is recommended beyond supportive care.

In recent years, it has been suggested that since fetal lung fluid is absorbed into the circulation via lymphatic pathways and levels of certain biomarkers indicating fluid overload (such as pro-BNP) are elevated, these infants may require lower daily fluid intake than usual. Based on this idea, two

studies have been conducted, showing that infants receiving lower fluid volumes required shorter respiratory support and were discharged earlier.

This study aims to evaluate the effectiveness of restricted fluid therapy in the treatment of transient tachypnea of the newborn.

For healthy newborns, the daily fluid requirement is approximately 60 mL/kg for term infants and 70–80 mL/kg for preterm infants, typically increasing by 10–15 mL/kg per day. In the restricted fluid group, approximately two-thirds of this amount will be administered on the first day, and subsequent adjustments will be made based on the infant's weight and urine output.

If you agree to participate, your baby will be randomly assigned (using a sealed envelope method) to receive either standard fluid therapy or restricted fluid therapy. The group assignment will not be known in advance.

- In the standard fluid group, the initial fluid volume will be 60–70 mL/kg/day.
- In the restricted fluid group, it will be 40–50 mL/kg/day.

In this study, only the initial fluid volume on the first day is predetermined. On subsequent days, fluid management in both groups will be adjusted according to the infant's needs (normally, infants are expected to lose about 5–8% of their birth weight within the first 3–4 days). Apart from this, both groups will receive similar monitoring and treatment.

No additional blood samples will be taken, and no extra interventions will be performed for the purposes of this study. The study will record parameters related to recovery, such as duration of respiratory support, time to initiation of feeding, and length of hospital stay.

Participation in this study is entirely voluntary. Your decision not to participate will not affect your baby's treatment in any way. If you choose not to participate, your baby will receive standard fluid therapy, and routine clinical care will continue. However, follow-up data (such as duration of respiratory support, time to feeding, and length of stay) will not be recorded.

Restricted fluid therapy may theoretically have some adverse effects, such as elevated serum sodium or urea levels, hypoglycemia, excessive weight loss, or decreased urine output. However, previous studies have shown that none of these adverse effects occurred in infants receiving restricted fluid therapy. Nevertheless, in this study, all infants will be closely monitored for hypoglycemia, urine output (measured six times daily by weighing diapers), and weight changes (measured twice daily). Kidney function tests will be checked at 24 hours, and on days 3 and 5.

In the unlikely event that your baby is harmed as a result of participation in this study, compensation will be provided.

You have the right to withdraw your baby from the study at any time without affecting the standard medical care provided.

This study has been approved by the Malatya Clinical Research Ethics Committee, which also has the authority to monitor the study. All medical records related to your baby will be kept strictly confidential and will not be accessible to third parties. In accordance with regulations, identifying information will remain confidential and will not be disclosed publicly, even if study results are published.

You will be informed promptly if any new information arises that may affect your decision to continue participation.

For further information about the study, your rights, or in case of any adverse event, you may contact the following physicians 24/7:

- Dr. İsmail Kürşad Gökçe: +90 506 742 2353
- Dr. Ramazan Özdemir: +90 505 378 1128
- Dr. Hüseyin Kaya: +90 554 364 4968

A total of 70 infants are planned to be included in the study: 35 in the restricted fluid group and 35 in the standard fluid group.

In most infants with transient tachypnea of the newborn, respiratory distress resolves within 4 days, and most infants are discharged within one week. However, in some cases, the disease may be more severe and prolonged.

Regardless of participation, your baby will receive standard neonatal intensive care according to current guidelines. The only difference in participation is the initial fluid volume administered and the recording of specific clinical data (daily fluid intake per kilogram, urine output, kidney function tests on days 1, 3, and 5, duration of invasive and non-invasive respiratory support, and total length of hospital stay).

Informed Consent Statement:

“I have read and understood all the information provided in this Informed Consent Form. I have received both written and verbal explanations regarding the study described above from the physician named below. I understand that participation is voluntary and that I may withdraw at any time without providing a reason. I agree to participate in this study of my own free will, without any pressure or coercion.”

Name and Surname of the Parent:
Date:
Signature:

Name and Surname of the Researcher Providing Information:
Date:
Signature:

Name and Surname of the Witness (if applicable):
Date:
Signature: