UNIVERSITY
CHILDREN'S HOSPITAL
ZURICH

Invitation to Participate in Medical Research

Study Title: Taping for Umbilical Hernia

Lay Title: Taping of Umbilical Hernias

Dear Parents,

Dear Guardians,

Your child has an umbilical hernia. Umbilical hernias are very common in infants and are usually harmless. In most cases, they disappear on their own during childhood. However, if the hernia persists until school age, surgery may become necessary.

We would like to inform you about our study, "Taping of Umbilical Hernias," and ask if you agree to your child participating. This type of research is called a clinical study. In this study, we want to find out whether a non-surgical treatment—so-called "taping" of the hernia—makes the hernia disappear faster than simply waiting.

Participation of your child is voluntary. The following **patient information** is intended to help you decide. You can ask the study doctor, Dr. Hannah Neeser (or her representative), any questions you may have. The study doctor is responsible for this study and will care for your child during participation. If you would like your child to take part, please sign the **consent form** at the end. Your signature confirms that you have read and understood the information. If anything is unclear, please ask the study doctor.

The patient information and consent form consist of four parts:

Part 1 **Key points**
Part 2 **Detailed Study Information**
Part 3 **Data protection and Insuracnce**
Part 4 **Consent Form**

Reading **Part 1** gives you an overview of the study. **Part 2** explains the study process and background in detail. **Part 3** contains information on data and insurance protection. By signing at the end of **Part 4**, you confirm your understanding and agreement for your child to participate.

This study is initiated by Prof. Dr. Ueli Möhrlen, Director of the Surgical Clinic at the University Children's Hospital Zurich, who is the sponsor. The sponsor is responsible for conducting, managing, and funding the study.

You may ask questions about this study at any time. In case of uncertainties or emergencies during or after the study, please contact:

University Children's Hospital Zürich

Dr. med. Hannah Neeser

Attending Surgeon

Surgical Clinic

Lenggstrasse 30

8008 Zürich

Phone: +41 44 249 49 49

E-Mail: hannah.nesser@kispi.uzh.ch

In an **emergency** (24h available) please call +41 44 249 49 49 and ask for the Emergency Department.

Part 1:
Key Points

1. Why are we conducting this study?

Your child has an umbilical hernia, and we are asking if you would like your child to participate. Umbilical hernias in infants are very common and usually resolve on their own by school age. If not, surgery may be required. Until then, the hernia is usually just monitored, not treated. This is the current standard in Switzerland.

With this study, we want to find out if taping the hernia helps it disappear faster. We also want to know if taping leads to fewer protruding belly buttons ("outies") and whether parents feel better and worry less when the hernia is taped compared to when it is not treated.

You can find more about the scientific background in **Part 4**.

2. What do you have to do if your child participates?

If you agree, your child will be randomly assigned to one of two groups:

Taping-Group: The umbilial hernia will be taped. We will teach you how to tape the hernia so you can do it at home. The tape should be changed by you about every 5 days.

Control Group: The umbilical hernia will be observed, not treated.

Regardless of group, your child will have three appointments at the Children's Hospital Zurich:

- At the first appointment your baby is older than 1 month and younger than 3 months old
- At the second appointment your baby is 6 months old
- At the third appointment your baby is 12 months old

Each visit lasts about 30 minutes. The first visit in the taping group takes a bit longer for instruction. After each visit, you will receive an online questionnaire to fill out. You will also be asked to keep a diary and to make at least one entry per week.

See **Chapter 5** for more details about the study process.

3. What are the benefits and risks of participation?

Benefits

Your child may not benefit directly from participating in this study. However, it is possible that your child's umbilical hernia might resolve faster.

The results can help other children in the future by improving treatment recommendations.

Risks

Taping is a known treatment but not standard in Switzerland. The risks involved in participating in this study are very low. The main risk is skin irritation, e.g. skin redness or rarely open skin lesions, from the tape used when taping the umbilical hernia, which usually resolves with a short break.

See **Chapter 6** for more on risks and burdens.

Part 2:
Detailed Study Information

4. The scientific background of this study

4.1 Why are we conducting this study?

Umbilical hernias are common in infants (10–20% affected). They occur due to a weakness at the navel, allowing tissue or intestine to bulge. They rarely cause pain or concern.

Over 90% close on their own by age 5, so most are not treated. If the hernia persists until school-age, surgery is recommended.

Taping was used in the past to speed healing, but its benefit was unproven, so it is now rarely used in Switzerland. Recent studies from Japan suggest taping may help the hernia resolve faster, reduce parental worry, and result in a more attractive navel (fewer "outies"). Taping is now standard in Japan. More and more Swiss physiotherapists and midwives offer taping, but high-quality studies are lacking.

Study goal

To determine if taping helps hernias resolve faster compared to waiting, and how parents feel about taping vs. no treatment.

Eligibility

All children with a visible umbilical hernia can participate. At the first visit, your child must be older than 1 month and younger than 3 months.

If your child was born prematurely, participation is possible up to the end of the corrected third month. The subsequent study visits will take place according to your child's corrected age (i.e. if your child was born one month early, we will not see them for the 6 month visit until they are 7 months old, as only then will 6 months have passed since their expected date of birth).

4.2 Study design: What will we do?

In this study, participants are randomly divided into groups. This is important in order to obtain reliable results from the study. This is called randomisation. There are two groups in this study:

Group 1: «Taping group»

- Your child's umbilical hernia will be taped

Group 2: «Control group»

- Your child's umbilical hernia will not be treated

4.3 Regulations on research with humans

The study follows Swiss law (Human Research Act, Data Protection Act) and international guidelines. The responsible ethics committee has reviewed and approved the study.

The study is conducted only at Children's Hospital Zurich, with a planned 82 participants. Study details are available at www.humanforschung-schweiz.ch under HumRes number 67783 or BASEC number 2025-01453.

5. Ablauf der Studie

5.1 What do you have to do if your child participates?

Participation is voluntary and lasts 9–11 months, depending on your child's age at entry. You must follow the schedule (see 5.2) and the study doctor's instructions.

5.2 Study schedule

If you agree to participate, your child will have three appointments at the hospital. You will keep a diary about the hernia's progress and receive an email questionnaire after each appointment, which we ask you to answer as soon as the appointment ends.

First appointment (Age of your child: older than 1 month and younger than 3 months; for premature babies: older than 32 weeks gestation and younger than 52 weeks gestation)

At this appointment, we will photograph your child's umbilical hernia and examine it clinically. We will then perform a short, painless ultrasound examination to measure the size of the umbilical hernia. This will only take a few minutes.

We will ask you a few questions to ensure that your child is suitable for the study. Our team of doctors will also provide you with the usual information about umbilical hernias, their natural progression and the risks involved.

Your child will then be randomly assigned to one of two groups. This is important in order to obtain reliable results from the study. This is called randomisation. Each group will receive a different treatment. The chance of being assigned to one of the two groups is the same (like tossing a coin).

Group 1 (Taping Group)

A physiotherapist from the Children's Hospital Zurich will show you how taping works and how you can tape your child's umbilical hernia yourself at home. You will also receive a leaf-

let containing the most important points to bear in mind when taping at home. You will receive detailed instructions and can contact us at any time if you have any questions or problems.

You will tape the umbilical hernia until it disappears or the study ends (i.e. in the longest case taping has to be continued for 9 to 11 months). On average, you will need to change the tape every 5 days.

Gruppe 2 (Control group):

The umbilical hernia will not be treated. You don't have to do anything at home. This approach of waiting and observing is consistent with the current medical standards.

Second appointment (Age of your child: 6 Months; for premature babies: corrected 6 months)

In a brief conversation, we will ask you, as parents/guardians, about the course of treatment (taping group) or non-treatment (control group) of the umbilical hernia. We will then photograph and examine your child's umbilical hernia. We will also perform a brief, painless ultrasound examination to measure the size of the umbilical hernia. This will only take a few minutes and will not hurt your child.

Third appointment (Age of your child: 12 Months; for premature babies: corrected 12 months)

Same schedule as the second appointment.

Diary

At your first appointment, you will receive a diary in which you can record important information about your hernia. You can also document any skin irritation here.

You will be asked to make an entry at least once a week. Please bring this diary with you to every appointment. We will copy your notes at each appointment and take them into account when evaluating the study results.

Online-Questionnaire

After each appointment, you will receive a short questionnaire by email about your quality of life and any concerns you may have. If the umbilical hernia closes during the study period, you will also receive a questionnaire asking how you like your child's navel. It takes about 10 minutes to complete these questionnaires.

On the consent form, you can specify the email address to which we should send the questionnaires.

Schedule of the study:

Appointment	1	2	3
Age of your child (in months)	1-3	6	12
Duration	30min (Contro group) 60min (Taping group)	30min	30min
Photo of the umbilical hernia	+	+	+
Clinical exam	+	+	+
Ultrasound of the umbilical hernia	+	+	+
Instruction for Taping (jiust Taping-Group)	+		
Online Questionnaire	+	+	+
Diary (at least one entry per week)	+	+	+

We will arrange the appointments together with you. You will receive a detailed overview of the appointments. The appointments cannot simply be rescheduled. We kindly ask you to inform us as soon as possible if you nevertheless have to reschedule an appointment for important reasons.

5.3 When does participation in the study end?

The study runs during your child's first year of life and ends after the third appointment, independent of the closure or failure of closure of your child's umbilical hernia. After that, you do not need to do anything else.
If the umbilical hernia has not disappeared by the third appointment in children in the control group and you wish, you can receive free instructions on taping from a physiotherapist at the Children's Hospital Zurich.
You can also withdraw your child from the study at any time (see section 5.4). You do not need to explain why you no longer wish your child to participate in the study. If you wish to withdraw your child from the study early, please speak to the investigator. If you terminate your child's participation early, this will not affect your child's further medical care and treatment (see section 5.4).
If your child's participation ends early, we will still evaluate the data collected up to that point (e.g. photos, ultrasound images, questionnaires) for the study. The study data will remain encrypted (see section 9).
We may also have to exclude your child from the study prematurely. This may happen if we see that your child's skin is becoming too irritated by the taping. Your child's further medical treatment/care is guaranteed at all times.

However, the data collected up to that point will remain valuable for the study and will be used for evaluation despite exclusion from the study. No further measures need to be taken after exclusion from the study.

5.4 What happens if you do not want your child to participate in the study?

Even if your child does not participate in this study, we will treat and care for your child medically in the best possible way according to current standards.

If, after initial contact with us, you decide that your child should not participate in this study, your contact details will be deleted immediately.

6. Risks, side effects and adverse reactions

Which risks and burdens may arise?

If your child participates in the study, the group assignment will be decided at random (like tossing a coin).

Children in the control group are not exposed to any additional risks, as they will not receive any special treatment.

Children in the taping group may experience skin changes under the tape. Mild reddening of the skin is very common and usually disappears on its own within a few hours. Please document any skin irritation in the diary.

In rare cases, the tape may cause small open wounds. In this case, taping must be interrupted for a longer period of time. If this occurs, we would be grateful if you could inform us briefly by telephone or email.

In very rare exceptional cases, the skin may react so severely that taping cannot be resumed. In this case, we will exclude your child from the study (see section 5.3).

If your child is restless during the study period and you cannot find any other cause, the tape must be removed to ensure that no skin changes have occurred.

If your child is in the taping group, you may only use the skin tape provided by us for taping of the umbilical hernia during the study period.

Other serious risks, such as intestinal obstruction, are only described as isolated cases in the medical literature. However, this complication can also occur without taping in the case of an umbilical hernia.

Regardless of the group assignment, you as parents/guardians will be informed about such rare but dangerous situations and will receive precise instructions on what to do in these cases..

The ultrasound examinations, which shall be performed during the study visits, pose no risk to your child.

7. Funding and compensation

The study is mainly funded by a research grant and by the Surgical Clinic of the Children's Hospital Zurich.

Participation in the study will not incur any additional costs for you/your child or your child's health insurance provider. If your child is assigned to the taping group, we will provide you with the tape to take home.

If your child participates in this study, you/your child will not receive any compensation..

8. Results of the study

There are results that concern your child. Your trial doctor will inform you of these results. There are also incidental findings. Incidental findings are 'accompanying results' that are not intended. These can be abnormalities in the ultrasound, for example. We will inform you if these incidental findings are relevant to your child's health.

If you do not wish to be informed, please discuss this with your study doctor. Some results and incidental findings are always communicated, for example, if other people are at risk or if it must be reported by law.

There are also the overall results of the study, which come from the data of all participants. This includes, for example, learning more about the advantages and disadvantages of taping umbilical hernias. These results do not directly affect your child's health. However, at the end of the study, your trial doctor will be happy to provide you with a summary of the overall results of the study if you wish.

In addition, the results will be published in layman's terms at the end of the study at www.humanforschung-schweiz.ch (expected from September 2030).

Part 3:
Data protection and Insurance

9. Protection of Data

We protect your child's data (e.g. information such as the size of the umbilical hernia from your child's medical history). There are strict legal regulations in Switzerland for the protection of data.

The Swiss Data Protection Act gives you the right to access, correct and retain your child's data that is collected, processed and transferred as part of the study. In exceptional cases, these rights cannot always be guaranteed due to other legal or regulatory requirements. If you have any questions about this, please contact your investigator..

9.1 Encryption of Data

Every study generates data from the examinations (e.g. clinical examinations, etc.). This data is documented. This is usually done electronically in large tables, known as 'data collection forms'. All data is documented in encrypted form. 'Encrypted' means that personal information that could directly identify your child is stored separately from the examination results. There is a list (key list) that identifies each person with a unique code. This means, for example, that your child's name does not appear directly on the data collection form. This key list remains at the Children's Hospital Zurich for 20 years and is then destroyed. No one else receives this key list.

Date of birth

In this study, your child's date of birth is recorded in the data collection form for the purpose of calculating their age. After completion of the study and before the data is archived, the date of birth is deleted so that your child cannot be identified.

E-Mail address

After each appointment at the Children's Hospital Zurich, you will receive a questionnaire by email. Your email address will be stored in the research database for the purpose of sending these questionnaires. We will use this address exclusively for the electronic transmission of questionnaires and will never pass it on to third parties. On the consent form, you can specify the email address to which we should send the questionnaires. After completion of the study and before archiving the data, the email address will be deleted.

9.2 Secure handling of data during the study

The sponsor, Prof. Dr. med. Ueli Möhrlen, is responsible for the secure handling of your child's data from this study. He is responsible for ensuring that applicable laws, e.g. data protection laws, are complied with.

In this study, your child's data will be recorded and transmitted electronically. The data is stored on the server/storage device of the Children's Hospital Zurich in Switzerland, where it is protected as best as possible. Nevertheless, there is always a certain residual risk that unauthorised persons may access personal data (e.g. risk of 'hacking').

9.3 Secure handling of data after the end of the study

The sponsor remains responsible for the secure handling of your child's data even after the end of the study. The law stipulates that all study documents, e.g. data collection forms, must be retained for at least 20 years. After this long period, the study data will be destroyed.

The photos taken of your child's umbilical hernia during each examination will be kept in your child's study documentation. Some of these photos may later be used for the publication of the study results without names and without your child being recognisable. The photos will also, after the study ends, be shown to two independent pediatric surgeons, who will perform the same assessment of the appearance of your child's belly button as you did. These surgeons cannot identify your child or the group allocation based on the photos.

After a study is completed, the results are usually published in scientific journals. The results are reviewed by other experts for this purpose. Your child's encrypted data may need to be forwarded to these experts. However, the data may not be reused for new research purposes. This would require your separate consent. However, the encryption prevents the experts from identifying your child.

9.4 Reuse and disclosure of data for other future studies

We require your separate consent for the further use and/or transfer of your child's data. This is voluntary. Please read the additional consent form at the end of this document carefully. Please sign the consent form if you would like to support further research in the future with your child's data. Even if you do not give your consent, your child can still participate in this study.

9.5 Right of access during inspections

The conduct of this study may be inspected. Inspections are carried out by authorities such as the relevant ethics committees. The sponsor must also carry out such inspections to ensure the quality of this study and its results. For this purpose, a small number of specially trained individuals will have access to your child's personal data and medical history. The data is therefore not encrypted for this review. The individuals who view your child's unencrypted data are subject to confidentiality obligations.

As the parent/legal representative of a study participant, you have the right to view your child's data at any time..

10. Insurance Cover

Although this study does not involve any foreseeable risk, the University Children's Hospital Zurich is liable in accordance with the statutory provisions for any damage that may arise in the course of this study.

If your child suffers any damage as a result of participating in this study, please contact the principal investigator, Dr Hannah Neeser (University Children's Hospital Zurich).

Teil 4:
Consent Form

This consent consists of two independent declarations of consent:

- Declaration of consent to participate in this study
- Declaration of consent for the further use and transfer of data from this study in encrypted form for further research.

Please read this form carefully. Please ask us if you do not understand something or if you would like to know more. Your written consent is required for participation.

Declaration of consent to participate in the study 'Taping for Umbilical Hernia'

BASEC-Number	2025-01453
Title of the Study	Taping for Umbilical Hernia
Lay Title	Taping for Umbilical Hernia
Responsible Institution (Sponsor with address)	University Children's Hospital Zürich Prof. Dr. med. Ueli Möhrlen Chirurgische Klinik Lenggstrasse 30 8008 Zürich
Study location	University Children's Hospital Zürich
Investigator at the study site	Dr. med. Hannah Neeser University Children's Hospital Zürich
Participant: Name and Surname in block letters: Date of birth:	

I have received verbal and written information about the study from the doctor who has signed this consent form.

• The investigator (or their representative) has explained the purpose, procedure and risks of the study to me.

• My child is participating in the study voluntarily.

• The investigator (or their representative) has explained to me what standard treatments are available outside of the study.

• I have had sufficient time to make this decision. I will keep the written information and receive a copy of my written consent form.

• I can withdraw my child from this study at any time. I do not have to explain why. Even if I withdraw my child from the study, they will continue to receive medical treatment. The data collected up to that point will still be evaluated as part of the study.

• If I withdraw, my child's data will remain encrypted.

• If it is better for my child's health, the investigator can exclude my child from the study at any time.

• I understand that my child's data will only be shared in encrypted form for this study. The sponsor ensures that data protection is maintained in accordance with Swiss standards.

• I will be informed of any results and/or incidental findings that directly affect my child's health. If I do not wish to be informed, I will discuss this with the investigating physician.

• The responsible specialists of the sponsor and the ethics committee may view my child's unencrypted data for review purposes. All these persons are subject to confidentiality obligations.

• The liability insurance of the Children's Hospital Zurich covers any possible damages.

• An email address will be recorded in the study database for the purpose of sending the online questionnaires. The following email address should be used for this purpose:

_____@_____

Place, date	**First and last name** of at least one **parent / legal guardian** *(in block letters)* Details of **relationship to patient** (father / mother / guardian, etc.) Legally valid **signature** of at least one **parent / legal guardian**

Confirmation by the investigator: I hereby confirm that I have explained the nature, significance and implications of the study to the parents/legal guardians of this participant. I assure that I will fulfil all obligations related to this study in accordance with Swiss law. Should I become aware of any aspects during the course of the study that could influence the participant's willingness to participate in the study, I will inform them immediately.

Place, date	Name of investigator *(in block letters)* Legally valid signature of the investigator

Declaration of consent for the reuse and/or transfer of data in encrypted form

This consent does not apply to your child in terms of personal participation in a study. (Section 9.4 of the patient information).

'Further use' means that your child's data may be stored beyond the duration of their participation in the study and used in encrypted form for further research. This may mean, for example, that images of your child's umbilical hernia are statistically evaluated together with a large number of other values or that new studies are conducted using them.

'Transfer' means that your child's data may be transferred in encrypted form to other researchers or research institutions for further research projects. These other researchers or research institutions may also be located abroad. It is the sponsor's responsibility to ensure that this country has an adequate level of data protection comparable to that in Switzerland.

BASEC-Number:	2025-01453
Title of the study	Taping for Umbilical Hernia
Lay title	Taping for Umbilical Hernia
Participant: Name and Surname in block letters: Date of birth:	

- I consent to the encrypted data of my child from this study being used and shared (including abroad) for medical research purposes.

- I understand that the data is encrypted and that the key is kept secure.

- The data may be analysed in Switzerland and abroad and stored in a database here or abroad. Research institutions abroad must comply with the same data protection standards as those applicable in Switzerland.

• I voluntarily consent to the further use and/or transfer of data in encrypted form and may revoke this consent at any time. I will only inform my child's investigating physician and do not need to justify this decision.

- If I withdraw, my child's data will remain encrypted.

- Normally, all data is evaluated collectively. If a result happens to emerge that is very important for my child's health, I will be contacted. If I do not wish this, I will inform my child's trial doctor.

Place, date	**First and last name** of at least one **parent / legal guardian** *(in block letters)* Details of **relationship to patient** (father / mother / guardian, etc.) Legally valid **signature** of at least one **parent / legal guardian**

Confirmation by the investigator: I confirm that I have explained the nature, significance and scope of the further use of data to the parents/legal representatives of the participant.

Place, date	Name of investigator *(in block letters)* Legally valid signature of the investigator