Research Protocol: A Comparative Study of the Advantages of Water-Separation Circumcision

Study Title: Comparative Evaluation of Hydrodissection circumcision vs. Traditional Circumcision Techniques: A Randomized Controlled Trial

1. **Study Objective:** The objective of this study is to compare the clinical outcomes and advantages of water-separation circumcision (Group A) versus two traditional circumcision techniques (Group B: "Subcutaneous Tissue Sparing "and Group C: "Non-Subcutaneous Tissue Sparing ") in male patients.
2. **Background and Rationale:** Circumcision is one of the most commonly performed surgical procedures globally. Several techniques exist, including those that preserve or remove subcutaneous tissues. A newer method, water-separation circumcision, is being introduced as a potential improvement. This study aims to evaluate its effectiveness in terms of complications, healing time, and patient satisfaction, comparing it with traditional circumcision techniques.
3. **Study Design:** This is a **prospective, randomized controlled trial** designed to evaluate the clinical outcomes of water-separation circumcision (Group A) compared to two traditional circumcision techniques (Group B and Group C).

4. **Inc**lusion Criteria:

① Complies with the diagnostic criteria for phimosis, foreskin elongation, and related diseases in the "Chinese Expert Consensus on Phimosis, Foreskin related Diseases";

② Preoperative routine examination showed no abnormalities in coagulation, blood routine, electrocardiogram and other indicators;

③ No severe genital herpes, gonorrhea, syphilis, glans infection, etc.;

④ Complies with the indications for sleeve type circumcision;

⑤ The patient or family member is aware of the surgical plan and signs the informed consent form.

5. Exclusion Criteria:

① Patients with concomitant urethral malformations, such as hypospadias;

② Patients with combined inflammation of the penis, prior penile surgery, severe adhesions, buried penis, and short frenulum of the penis;

③ Exclude individuals with combined allergies or allergies to multiple medications;

④ Patients with severe physical illnesses such as heart and lung dysfunction who cannot tolerate surgery;

⑤ Individuals with cognitive impairments or mental abnormalities;

⑥ Diabetes with poor glycemic control；

⑦ Age >35 or Age<6.

6. Intervention Groups:

Group A (Hydrodissection circumcision): This group will undergo the water-separation circumcision technique, where water is used to separate the skin from the underlying tissues before performing the circumcision (HC).

Group B (Subcutaneous Tissue Sparing Circumcision):

This group will undergo a traditional circumcision procedure where the subcutaneous tissue is preserved, aiming for less scarring and quicker healing (sCC).

Group C (Non-Subcutaneous Tissue Sparing Circumcision):

This group will undergo the traditional circumcision procedure in which the subcutaneous tissue is not sparing (uCC).

7. Outcome Measures:

Primary Outcome Measure:

1. operation time

Operative time was calculated by timer.

[Time Frame: 1 day]

2. intraoperative bleeding

The amount of intraoperative bleeding is calculated by weighing gauze before and after operation. 1 milliliter is approximately equal to the weight of 1 gram.

[Time Frame: 1 day]

3. The healing time

The healing time was judged by the doctors based on the observation of the wound and inquiry of the patients during 7-25 days after surgery. We defined complete wound healing as the absence of a scab with a completely epithelialized and dry skin surface based on clinical assessment.

[Time Frame: 7-25 days]

4. Intra-operative pain

Intra-operative pain was graded immediately after the operation while the post-operation pain was graded at 1 week by NRS (Numeric Rating Scale). The scale typically ranges from 0 to 10. 0 indicates no pain, while 10 signifies the most severe pain imaginable.

[Time Frame: 1 day]

Secondary Outcome Measures:

5. other complications

incidence rate

[Time Frame: through study completion, an average of 1 year]

6. patient satisfaction

Patient satisfaction is divided into 5 levels：Extremely dissatisfied，Dissatisfied，Neutral，Satisfied，Extremely Satisfied.

[Time Frame: through study completion, an average of 1 year]

8. Sample Size Calculation:

Given an assumed type I error (α) of 0.05 and type II error (β) of 0.20, a power of 80% is desired to detect a significant difference in the primary outcome (complication rate). Using a conservative estimate based on previous studies of circumcision complication rates, a sample size of 96 patients (32 patients per group) will provide sufficient power to detect differences between the three techniques. This sample size assumes a 10% dropout rate, so 96 patients will be recruited in total.

9. Randomization:

Randomization will be performed using a computer-generated randomization list, ensuring that each participant has an equal chance of being assigned to one of the three groups. Stratified randomization

will be used to ensure balance across demographic variables (e.g., age, baseline health status). Patients will be blinded to group assignment, and the surgical team will remain unaware of the group allocation to reduce bias.

10. Statistical Analysis:

Data will be analyzed using the **Statistical Package for the Social Sciences (SPSS)** software, version 26 (or newer). The following statistical methods will be applied:

Descriptive statistics (mean, standard deviation, frequency distributions) will be used for demographic data and outcome measures.

Chi-square tests will be used to compare categorical variables (e.g., complication rates between the three groups).

Analysis of variance (ANOVA) will be applied to compare continuous variables (e.g., healing time, pain scores) between groups. If assumptions of normality are violated, **Kruskal-Wallis tests** (non-parametric version of ANOVA) will be used.

Post-hoc tests (e.g., Tukey's test) will be applied where significant differences are found in the ANOVA. **Kaplan-Meier survival analysis** will be used to assess time to healing (i.e., complete wound closure). **P-values of < 0.05** will be considered statistically

significant. **Confidence intervals (95%)** will be reported for all continuous outcomes.

11. **Ethical Considerations:** The study will be conducted in accordance with the **Declaration of Helsinki** and will be approved by the Chongqing Jiulongpo Hospital ethics committee. All patients will provide written informed consent prior to participation, and their rights, confidentiality, and well-being will be ensured throughout the study. The clinical trial will be registered in a public database.

12. Timeline:

Study start date: 2019-6-30

Study end date: 2024-2-07

Recruitment period: 3 months

Follow-up period: 1 year after surgery

13. Budget Considerations:

Personnel costs (surgeons, nurses, data managers):

1000 x 96=96000RMB

Materials and Equipment (surgical tools, sutures, bandages, anesthesia)

500 x 96=48000RMB

Statistical and software tools: 1000 RMB

Participant compensation for time and travel:

1000 X96=96000 RMB

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