RUMAH SAKIT UNIVERSITAS INDONESIA

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Name	:
Gender	:
Birth date	:

Informed Consent

Analysis of the Safety and Efficacy of Administering Umbilical Cord Mesenchymal Stem Cell Secretome in Patients With Severe Erectile Dysfunction Non-responsive to Sildenafil

Date : 6 October 2025

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INFORMED CONSENT FORM

Principal Investigator	: Dr. dr. Ria Margiana, Sp.And, M.Biomed
Information Provider	:
Information Recipient Name Birthdate (Age) Gender Address Phone	 : : : : :

	TYPE OF INFORMATION	CONTENT	MARK
1.	Research Title	Comparative Analysis of Safety and Efficacy between Administration of Secretome and Exosomes from Umbilical Cord-Derived Mesenchymal Stem Cells in Patients with Erectile Dysfunction	
2.	Research Purpose	The aim of this study was to analyze the differences in safety (local bleeding, hematoma, infection, pain) and efficacy after administering umbilical cord mesenchymal stem cell secretome and exosomes to patients with Erectile Dysfunction.	
3.	Research Methodology	This is an experimental study, assessing pre- and post-test scores. Patients who consent to the study will undergo an intracavernous injection of secretome/exosomes. Follow-up will be conducted at 2 weeks and 1 month after the study to evaluate several safety and efficacy parameters of the secretome/exosomes.	
4.	Risks and Side Effects in Research	Secretomes and exosomes have been used as adjuvant therapy and have not caused significant side effects. However, bleeding, bruising, tenderness, and swelling can occur in some individuals. During the study, researchers prepared the necessary safeguards in case of any adverse events. This protection included consultation and hospitalization services for potential side effects following the intervention. If bleeding, bruising, tenderness, and swelling occurred, subjects were informed beforehand to immediately apply a cold compress, which could be applied with cold water or ice cubes, for 10-20 minutes. If swelling occurred, a steroid injection was	

		given. If localized urticaria occurred, a topical antihistamine was given. If symptoms persisted and were accompanied by fever, the researchers and the hospital where the study was conducted would administer treatment in accordance with applicable Clinical Practice Guidelines, at the researchers' expense.	
5.	Benefits of research include benefits for research subjects	The benefits you can get include receiving adjuvant therapy for erectile dysfunction using UC-MSC secretome or exosomes and understanding its effects on your erectile function.	
6.	Research Procedures (written in detail using layman's language)	1. You will be interviewed by a doctor who will ask about your name, age, medical history, sexual history, medication history, allergies, smoking habits, and drinking habits. 2. You will undergo a physical examination by a doctor to assess your health and sexual health. 3. Before the injection therapy, you will be informed about the effectiveness and possible complications of the treatment and will complete several initial questionnaires for parameters [International Index of Erectile Function-5 (IIEF-5), Erectile Hardness Score (EHS), and Nocturnal Penile Tumescence (NPT)]. 4. On the day the study begins, you will be asked to come in for the interventional procedure. 5. The injection of stem cell-derived substances (UC-MSC secretome or exosomes) into the penis (intracavernosa) will be performed by a qualified doctor. The UC-MSC secretome used is a product developed by PT Kalbe. 6. You will be injected with 0.5 mL of UC-MSC secretome/exosomes into the penis (intracavernosa) using a 30-gauge needle according to a sterile protocol. Equal volumes are administered on both sides of the penile shaft, totaling 1 mL. The injections are given twice daily, on both sides of the penile shaft. 7. Tolerability is assessed by observing and questioning the subjects regarding pain during the intracavernosal injection. Pain intensity is rated on a visual analog scale of 0-10, where 0-3 represents mild pain, 4-6 represents moderate pain, and 7-10 represents severe pain. 8. After the injection, the	

		safety of the secretome will be assessed by examining the injection site for signs of bleeding, bruising, tenderness, swelling, coldness (hypothermia), heat (hyperthermia), redness (erythema), hives (urticaria), or fluid-filled hives (induration). Vital signs (temperature, heart rate, respiratory rate, and blood pressure) will be measured. You will also be interviewed for other possible side effects. The safety of the therapy will be assessed immediately, 24 hours after injection, and 1 month after injection through a physical examination. 9. The effects of intracavernous injection therapy will be assessed qualitatively using the International Index of Erectile Function-5 (IIEF-5), Erectile Hardness Score (EHS), and Nocturnal Penile Tumescence (NPT) questionnaires at baseline, 1 month, and 6 months after the intervention. 10. Patients will continue to receive their primary therapy, oral sildenafil.	
7.	Discomfort of research subjects (potential discomfort)	Discomfort may occur during intracavernous injections, but they will be administered by qualified medical personnel. After the injection, redness, bleeding, infection, and fever may occur.	
8.	Alternatif penanganan	The researchers provided consultation and hospital care for potential side effects following the intervention. Subjects were instructed to immediately apply a cold compress, typically with cold water or ice cubes, for 10–20 minutes, as first aid. If swelling persisted, a steroid injection was administered. If localized hives occurred, topical antihistamines were administered. If symptoms persisted and fever developed, the researchers and the hospital where the study was conducted would administer treatment in accordance with the applicable Clinical Practice Guidelines, with the researcher responsible for the costs.	
9.	Maintaining data confidentiality	All data collected in this study will be kept confidential. Presentations of research results at scientific meetings/conferences and publications in scientific journals will not include your name. However, ethics committees and national regulatory bodies regulating the use of medicines will have access to the research data for verification.	

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10.	Compensation if side effects occur	If the complaint does not improve and is accompanied by fever, the researcher and the hospital where the research is taking place will carry out management in accordance with the applicable Clinical Practice Guidelines, with costs borne by the researcher.	
11.	Name and address of researcher and contact telephone number	Dr. dr. Ria Margiana, Sp.And, M.Biomed Perumahan Taman Tanah Baru B2 no. 7, Tanah Baru, Beji, Depok +62 811-1775-515	
12.	Number of subjects	12 person	
13.	Potential danger	In general, this study did not cause significant side effects, but in some people bleeding, bruising, tenderness, and swelling may occur.	
14.	Costs incurred	None	
15.	Incentives for subjects	Rp300.000	

After reading the explanation on pages 1 to 4 regarding the research to be conducted by ..... entitled "Comparative Analysis of the Safety and Efficacy of Administering Secretome and Exosomes from Umbilical Cord-Derived Mesenchymal Stem Cells to Patients with Erectile Dysfunction," I have fully understood this information.

By signing this form, I agree to participate in the above research voluntarily without coercion from any party. If at any time I feel I have been harmed in any way, I have the right to withdraw this consent.

_____ _____

Signature Date

_____

Name

_____ _____

Guardian Signature Date

_____

Guardian Signature

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I have explained to the subject correctly and honestly the purpose of the research, the benefits of the research, the research procedures, as well as the potential risks and discomforts that may arise (a detailed explanation in accordance with the things I marked above. I have also answered questions related to the research to the best of my ability.

_____ _____

Researcher Signature

Date

.....

Researcher Name