



臺北醫學大學 泌尿腎臟研究中心 會議議程

時間：**115 年 6 月 17 日(星期三) 12:00-13:30**

地點：實體會議與視訊會議併行-(請以正式全名登入會議室，以利進行會議簽到)

使用 Google Meet (會議前 10 分鐘即開啟會議室)

會議室連結：<https://meet.google.com/ihn-wugo-jfv>

實體會議地點：雙和醫院第一醫療大樓 10 樓第一會議室

會議主席：吳美儀

與會人員：

【附醫】劉明哲、葉劭德、高治圻、吳建志、吳政誠、張景欣、方德昭、
吳逸文、陳錫賢、江仰仁、陳靜怡、林彥仲、邵月珠、周安琪、
吳致寬、李齊泰、林孝友、黃建榮、陳振文、陳寶寶、蔡東霖

【萬芳】溫玉清、李明哲、張渭文、林雍偉、蕭志豪、許軒豪、賴宗豪、
鍾卓興、鄭仲益、陳作孝、劉崇德、楊韻紅、楊宇祥、李良明、
林克勳、吳岳霖、廖宏偉

【雙和】李明哲、吳佳璋、陳冠州、劉家宏、江怡德、鄒凱亦、高偉棠、
胡書維、吳美儀、洪麗玉、鄭彩梅、廖家德、宋睿祥、蔡旻光、
陳佑璋、高芷華、林冠宏、曾健華、邱伯涵、陳至亨、董劭偉、
尹玉聰、林裕峯、宋立勤、柯玉誠、崔克宏

【北醫】羅偉成

【新國民】蘇裕謀、鄒居霖、江明傑、林宇璦、魏汶玲

長官指導：

吳麥斯校長、許志成教授、陳瑞明所長、盧星華副院長、許永和副院長

議程：

一、 特邀講師 — 台北慈濟醫院 洪思群教授

演講主題：Metabolomics in CKD: A Million Dollar Lesson

二、 團隊報告 — 功能性泌尿團隊(林雍瑋醫師)

三、 行政報告

1. 目前中心官網已委託廠商重新設計網站，若成員有相關績效亮點可協助提供，以利網站呈現（[相關資料請 mail 至 25120@s.tmu.edu.tw](mailto:25120@s.tmu.edu.tw) 或傳至 RCUK 群組）。

2. 下次例會實體與線上會議併行：

◆ 時間：**115 年 7 月 30 日 (四) 中午 12:30-14:00**。

◆ 實體會議地點：雙和醫院第一醫療大樓 10 樓第一會議室

◆ 線上會議網址：<https://meet.google.com/ihn-wugo-jfy>

◆ 團隊報告：**泌尿創新技術與手術團隊**。(若需要協助播放簡報，煩請團隊最晚於會議前一日提供)

3. 請三院三科主任協助將尚未加入 LINE 群組的成員盡快加入群組，以利後續相關活動跟資訊公告。(目前群組 48 人含秘書，RCUK 成員共 70 人)

RCUK LINE 群組：<https://line.me/ti/g/FC68Wb6efu>



Investigating the Effect of Amniotic Fluid Stem Cell-Derived Exosomes to treat Moderate to Severe Erectile Dysfunction

功能性泌尿團隊
萬芳醫院泌尿科 林雍偉醫師

Application of Stem Cell in Human Erectile Dysfunction

Author	Year	Design	Setting	N	Treatment	Duration	Key Findings		
							Findings	Results	Indicators
Balik et al ⁴	2010	NCBA	Single center	7	One injection of human umbilical cord SC intracavernous 1.5×10^7 cells	11 months	• Improved morning erection	• 3 of 7 patients after 1 month	IIEF
Levy et al ⁷	2015	Pros Cohort	Single center	5	One injection of PM-MSC intracavernous 2 mL in 6 months	6 months	• Improved peak systolic velocity penis	• Significant after 6 weeks	PSV, EDV, stretched penile girth, angle of curvature
Haahr et al ¹⁰	2016	RCT	Single center	17	One injection of ADSC intracavernous 8.4–37.2 million cells in 6 months	6 months	• Improved IIEF-5 score	• 8 of 17 patients after 6 months • Patients with urinary incontinence tended are less likely to experience improvement of erectile function.	IIEF-5
Levy et al ⁸	2016	Pros Cohort	Single center	8	One injection of PM-MSC intracavernous 1.5 mL in 6 months	6 months	• Improved peak systolic velocity penis	• Significant after 3–6 months treatment. • EDV, penile girth and length, IIEF-5 scores did not change significantly.	PSV, EDV, stretched penile girth, IIEF-5
Yiou et al ¹¹	2017	RCT	Single center	18	One injection of BM-MNC intracavernous, 10^9 cells in 6 months	1 year	• IIEF-5 scores and erectile function	• Improvement after 6 months. • Reduced after 6 months follow-up	IIEF-5

Protogerou et al ¹⁴	2017	CBA	Single center	15	One injection of ADSC with PLP or ADSC without PLP or PLP	1 year	• IIEF-5 scores • Morning erection	• Improved IIEF-5 scores in patients after the first month. • Improved morning erection in all patients on the third month.	IIEF-5
Ory et al ¹³	2019	Ret Cohort	Single center	36	Transendocardial hMSC with a dosage of 20–200 million cells	1 year	• IIEF-5 scores • Erectile function	• Improved IIEF-5 scores significantly with the use of autologous or allogenic hMSC transendocardial. • A dosage of 200 million cells showed significant improvement of erectile function after 12 months.	IIEF-5
Nasab ¹²	2020	RCT	Single center	20	One stem cell injection intracavernous oral mucosal 50–60 million cells in 6 months.	6 months	• IIEF-5 Score • Peak Systolic Volume • Resistance index	• Improved IIEF-5 score significantly between before therapy, 3 months, and 6 months post-therapy. • Improved peak systolic volume and resistance index in the treatment group, although not statistically significant.	IIEF-5, PSV, Resistance Index
Zasieda et al ⁸	2020	Pros Cohort	Single center	38	Six injections of MSC-DE 5 mL/week with LISWT 0.35 mJ/mm ² twice per week.	12 weeks	• IIEF-5 scores • EHS • Peak systolic velocity • End diastolic velocity	• Improved IIEF-5 and EHS scores significantly after treatment regimen. • Improved peak systolic velocity and reduced end diastolic penile velocity significantly posttherapy.	IIEF-5, EHS, PSV, EDV

Research and Reports in Urology 2022;14 379–388

羊水幹細胞 (MSC 4.0)

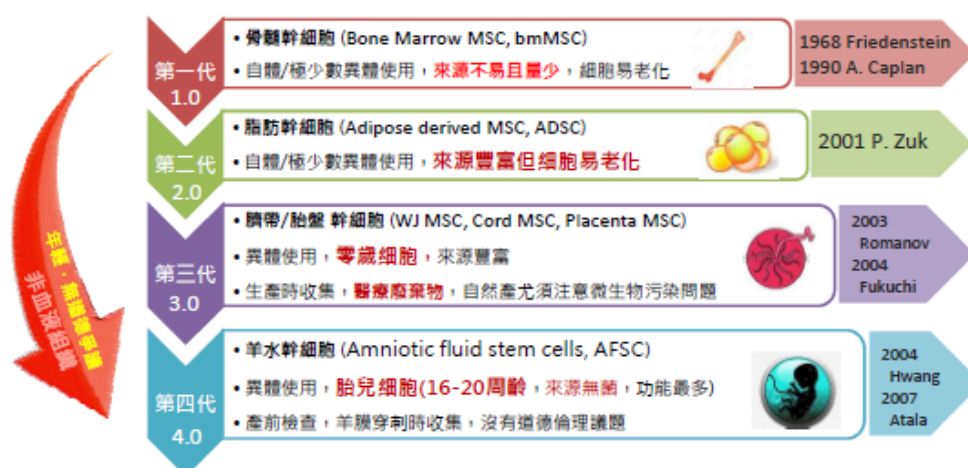


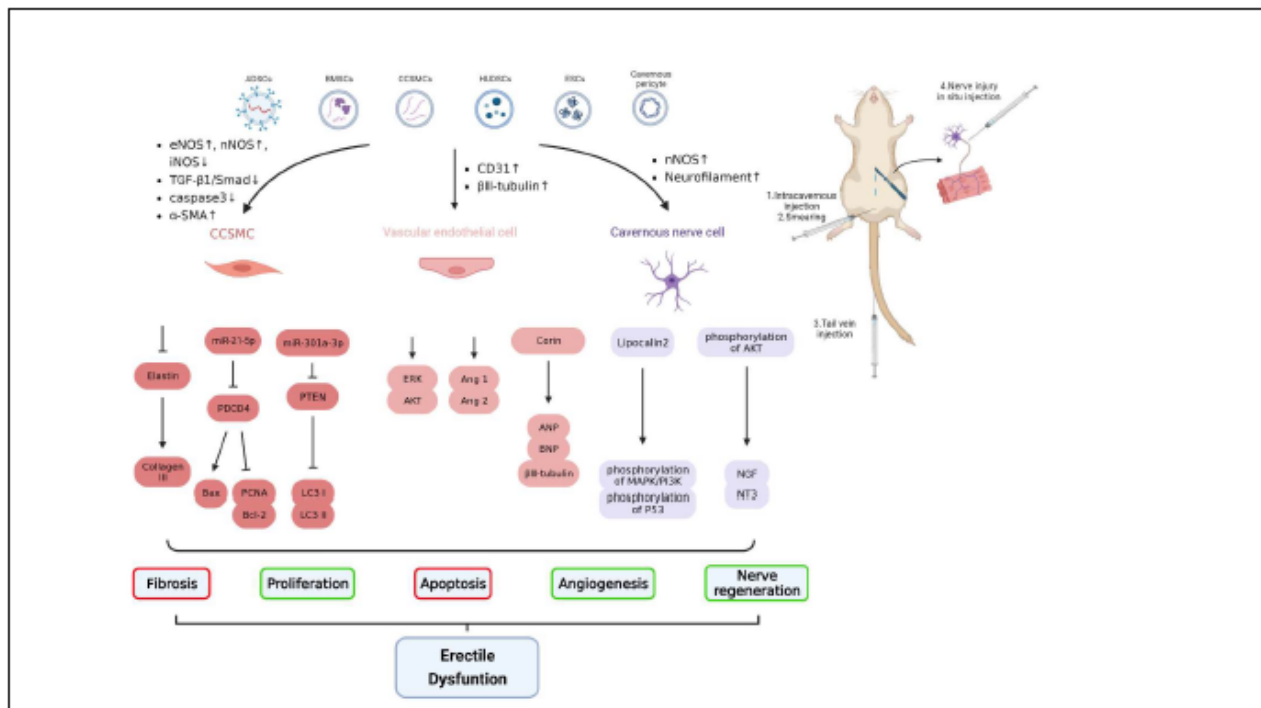
Table 1 The Comparison Between Stem Cell Therapy and Stem Cell-Derived Exosome Therapy

Treatment Modality	Advantages	Limitations
Stem cells therapy	Multilineage differentiation potential Suitable for the treatment of various diseases Accumulation of extensive laboratory and clinical data Easy to isolate, suitable for large-scale production Less pain and fewer complications Well-established regulatory guidelines	Short survival time after injection, low transplantation rate Strict storage and transportation requirements Potential tumorigenicity Infusion toxicity Immunogenicity Some stem cells may have ethical issues (eg, embryonic stem cells) Preparation process needs improvement Variability in therapeutic outcomes Batch-to-batch inconsistency
Stem cells-derived extracellular vesicles therapy	Comparable therapeutic effects to stem cells but with a smaller size More concentrated functional carriers (eg, cytokines) Can be modified on their surface and within the carriers Various delivery methods Long-term storage and high transport efficiency EVs derived from non-tumorigenic cells pose minimal tumorigenic risk Lack of ethical issues	Lack of standardized purification and storage protocols Relatively low yield in large-scale production Higher costs No industry-standard quality specifications Insufficient regulatory oversight

Effects of stem cell-derived exosome therapy on erectile dysfunction: a systematic review and meta-analysis of preclinical studies

Yunpei Zhu^{1,2}, Tiancheng Jiang^{1,2}, Chi Yao^{1,2}, Jiawei Zhang^{1,2}, Chao Sun, PhD^{1,2,*},
 Shuqiu Chen, PhD^{1,2,*}, Ming Chen, PhD^{1,2,3,*}

- ED was associated with decreased expression of endothelial markers (VEGF, eNOS, CD31, etc), smooth muscle markers (α -actin, smoothelin, etc), and pericyte markers (CD146 and NG2)
- Exosome administration improve erectile function by activating the NO/cGMP signaling pathway, ameliorating endothelium, and inhibiting the fibrosis and apoptosis of cavernosum



Ongoing clinical trial

•

3 533

•

55

•

4

Function of AFSC exosomes

- AFSC exosomes : cell-free nanoparticles secreted by AFSC containing **proteins, lipids, and microRNAs**.
- **Immunomodulation**: suppress inflammation and alter immune cell activity to create a healing microenvironment.
- **Tissue Repair & Regeneration**: accelerate wound healing and improve the regeneration of skin, hair follicles, nerves, and blood vessels.
- **Neuroprotection**: mitigate oxidative stress and inflammation in neurological conditions in Preclinical studies
- **Anti-Apoptosis**: prevent cell death and preserve function in damaged cells

The RNA Function Profile of Amniotic fluid stem cells, AFSC)

Anti-Fibrotic & Scarless Wound Healing

- **Primary Target**: Shutting down excessive **Transforming Growth Factor-beta (TGF- β) signaling**.
- **let-7-5p**: Directly suppresses tissue fibrosis and accelerates healthy cell proliferation.
- **miR-22-3p & miR-27a-3p**: Downregulate TGF- β receptor types I and II to block myofibroblast aggregation (preventing hard scar formation).
- **miR-21-5p & miR-23a-3p**: Regulate collagen distribution to mimic the soft matrix of fetal skin

The RNA function Profile of AFSC

Cell Preservation & Organ Development

➤ Anti-Apoptosis (Cell Survival)

- **miR-10a**: Prevents programmed cell death; protects ovarian follicles and vascular networks.
- **miR-146a**: Serves as a major anti-inflammatory switch to limit tissue degradation. [1]

➤ Organ & Tissue Development

- **miR-17~92 Cluster**: Essential for tissue branching and cellular differentiation.
- **Prenatal Research**: Proven to successfully rescue alveolar development in lung hypoplasia models.

The function of Protein Profile of AFSC

Regeneration, Angiogenesis & Immunomodulation

➤ Angiogenic & Repair Factors

- **VEGF**: Stimulates new blood vessel formation to supply oxygen and nutrients to damaged areas.
- **TGF- β 1 & FGF-2**: Orchestrate cell migration and proliferation to accelerate wound closure.
- **BDNF**: Protects neurons from oxidative stress and encourages nerve repair.

➤ Immunomodulatory Proteins

- **IL-10 & TGF- β (Cytokines)**: Act as biochemical "brakes" on the immune system.
- **M1 to M2 Switch**: Reprograms pro-inflammatory M1 macrophages into anti-inflammatory M2 healing macrophages.

Main Inclusion Criteria

1. Within 35-75 years old
2. Has been ever diagnosed with type 1 or type 2 DM
3. As received and is willing to continue to receive treatments for DM
4. HbA1c $\leq 10\%$ at the screening visit
5. IIEF-EF between 11~21 with maximum dose of oral PDE5i at the screening visit
6. ED history < 3 years
7. Diagnosed with ED at least 12 weeks prior to the screening visit

Confidential

Main Exclusion Criteria

1. Body mass index (BMI) ≥ 30 kg/m²
2. Hemoglobin A1c (HbA1c) > 10%
3. Has received cytotoxic agent, chemotherapy, or radiotherapy for other malignancies than prostate cancer within 4 weeks prior to the screening visit
4. ED due to structural abnormality of the penis such as Peyronie's disease or judged by the investigator
5. Received any penile implant
6. Had any surgery at the penile area within 24 weeks prior to the screening visit
7. Any of the following medical history, medications, or dietary contraindicated for taking Tadalafil
8. Any drug-induced or psychogenic erectile dysfunction within 4 weeks prior to the screening visit

Confidential

Indication	Diabetes Mellitus (DM)-Associated Erectile Dysfunction (ED)
Study Design	Phase I, Randomized, single-Blinded , and multiple centers study
Study Intervention	intracavernous injection of exosome or buffer every week for 6 weeks Combine with Tadalafil (QD) Follow up duration: 1 Year after injection
Study Population	Subjects with DM-associated ED
Arm	Experimental: Intervention : Exosome + Tadalafil Placebo: formulation buffer + Tadalafil
	Complete enroll 40 subjects within 1 year
Primary Endpoint	Change from baseline of the IIEF-EF score at 3 or 6M



臺北醫學大學
泌尿腎臟研究中心
TMU Research Center of
Urology and Kidney

Endpoints - Efficacy

- Efficacy Endpoints**

1st : IIEF-EF Domain, Change from Baseline at 3 or 6M

2nd : 其他性功能量表，Penile Doppler的變化

Visit	Screening	Treatment	Evaluation					Long-term FU	
	V1	V2	V3	V4	V5	V6	V7	V8	V9/EOS
Week	N/A	0	1	2	4	12	24	36	52
IIEF	X	X			X	X	X	X	X
EHS	X	X			X	X	X	X	X
SEP		X			X	X	X	X	X
GAQ					X	X	X	X	X
Penile Doppler (Optional)	X						X		X

Confidential