

Periode : Januari – Maret
Tahun : 2024
Skema Penelitian : Penelitian Dasar
Tema RIP Penelitian : Kualitas Kesehatan, Penyakit Tropis,
Gizi dan Kesehatan

**LAPORAN AKHIR
PENELITIAN DASAR**

Re: “A Novel Randomized Trial Protocol for Evaluating Wound Healing Interventions” by Bull et al.



TIM PENGUSUL:

Ketua Tim	: Adam Astrada	1101059201
Anggota Tim	: Budi Mulyana	0327119203
	Ratna Dewi	1005018002

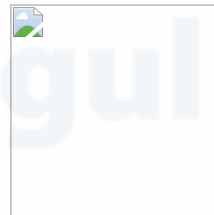
**Fakultas Ilmu-Ilmu Kesehatan Program Studi Ilmu Keperawatan
Universitas Esa Unggul
Tahun 2024**

**Lembar Pengesahan Laporan Akhir
Program Penelitian
Universitas Esa Unggul**

1. Judul Kegiatan Penelitian : RE: A NOVEL RANDOMIZED TRIAL PROTOCOL FOR EVALUATING WOUND HEALING INTERVENTIONS BY BULL ET AL.
2. Nama Mitra Sasaran :
3. Ketua Tim
 - a. Nama Lengkap : ADAM ASTRADA, S.Kep., Ns. MHS,CNS,DHSc,FACCWS
 - b. NIDN : 1101059201
 - c. Jabatan Fungsional : Lektor (200)
 - d. Fakultas/ Program Studi : Fakultas Ilmu-Ilmu Kesehatan/ Fikes/Program Studi Ilmu Keperawatan
 - e. Bidang Keahlian :
 - f. Nomor Telepon/ HP : 08975235030
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4. Jumlah Anggota Dosen : -
5. Jumlah Anggota Mahasiswa : -
6. Lokasi Kegiatan Mitra
 - Alamat
 - Kabupaten/ Kota
 - Provinsi
7. Periode/ Waktu Kegiatan : 6 Januari 2024 s/d 27 Januari 2024
8. Luaran yang Dihasilkan : Jurnal Internasional Bereputasi dan Berfaktor Dampak (Q1)
9. Usulan/ Realisasi Anggaran
 - a. Dana Mandiri :
 - b. Sumber Dana Lain (1) :

Jakarta, 25 Maret 2024

Ketua Peneliti,



(ADAM ASTRADA, S.Kep., Ns.
MHS,CNS,DHSc,FACCWS)
NIDN/K. 1101059201

Menyetujui,
Dekan Fakultas Ilmu-Ilmu Kesehatan



(Prof. Dr. APRILITA RINA YANTI EFF,
M.Biomed, Apt)
NIP/NIK. 215020572

Mengetahui,
Ketua Lembaga Penelitian dan Pengabdian
Masyarakat Universitas Esa Unggul

(LARAS SITOAYU, S.Gz, M.K.M)
NIK. 215080596

IDENTITAS DAN URAIAN UMUM

1. Judul Penelitian : Increasing angiogenesis factors in hypoxic diabetic wounds using siRNA nanotherapeutics

2. Tim Peneliti

No	Nama	Jabatan	Bidang Keahlian	Instansi Asal	Alokasi Waktu (jam/minggu)
1	Adam Astrada	Ketua	Keperawatan Medikal Bedah	Universitas Esa Unggul	20 jam/minggu
2	Budi Mulyana	Anggota	Keperawatan Kritis	Universitas Esa Unggul	2 jam/minggu
3	Ratna Dewi	Anggota	Keperawatan Medikal Bedah	Universitas Esa Unggul	2 jam/minggu

3. Objek Penelitian (jenis material yang akan diteliti dan segi penelitian):

Objek pada penelitian ini adalah penelaahan sistematis disertai meta-analysis untuk mencari bukti terkait penggunaan terapi topikal dalam menangani masalah biofilm pada luka.

4. Masa Pelaksanaan

Mulai : Januari tahun: 2024

Berakhir : Januari tahun: 2024

5. Usulan Biaya: Tahun ke-1 : Rp -

6. Lokasi Penelitian (lab/studio/lapangan): Kantor.

7. Instansi lain yang terlibat (jika ada, dan uraikan apa kontribusinya)

8. Temuan yang ditargetkan (produk atau masukan untuk kebijakan)

Hasil penelitian ini diharapkan dapat menemukan suatu bukti untuk penerapan *evidence-based practice* dalam penanganan masalah pada luka.

9. Kontribusi mendasar pada suatu bidang ilmu

Penelitian ini didasari atas meningkatnya masalah sirkulasi pada luka kaki diabetic.

10. Jurnal ilmiah yang menjadi sasaran: Molecular Therapy Nucleic Acids

Tahun : 2024

Luaran HKI : -

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DAFTAR TIM PELAKSANA DAN TUGAS

1. Ketua Pelaksana

Nama : Adam Astrada, Ns., MHS, CNS, DHSc., FACCWS
NIDN : 1101059201
Jabatan Fungsional : Lektor (200)
Fakultas/ Prodi : Ilmu-Ilmu Kesehatan/Ilmu Keperawatan
Tugas : Bertanggung jawab terhadap pembuatan proposal, pelaksanaan riset, mengolah data dan menyusun laporan akhir, membuat pertanggung-jawaban keuangan, menyusun publikasi

2. Anggota 1

Nama : Budi Mulyana, Ns., BSN, M. Kep.
NIDN : 0327119203
Jabatan Fungsional : Asisten Ahli (150)
Fakultas/ Prodi : Ilmu-Ilmu Kesehatan/Ilmu Keperawatan
Tugas : Bertanggung jawab terhadap menyusun publikasi

3. Anggota 2

Nama : Ratna Dewi, Ns., M. Kep., Sp. KepMB
NIDN : 1005018002
Jabatan Fungsional : Lektor (300)
Fakultas/ Prodi : Ilmu-Ilmu Kesehatan/Ilmu Keperawatan
Tugas : Bertanggung jawab terhadap menyusun publikasi

BAB I

PENDAHULUAN

1. Latar Belakang

I am writing in response to the article titled "A Novel Randomized Trial Protocol for Evaluating Wound Healing Interventions," published in *Advances in Wound Care*. I commend the authors for addressing crucial challenges in wound healing trials, particularly the limitations associated with dichotomous outcomes and difficulties in subject recruitment and follow-up. However, I would like to express some concerns and offer additional insights for consideration.

2. Permasalahan

Firstly, the author acknowledges that the study was not powered, and comparisons were not made between randomized cohorts. These deviations from the standard analytical approach in clinical trials raise important questions about the robustness of the study's conclusions. As the randomized controlled trial is a cornerstone in evidence-based medicine, adherence to established analytical principles is paramount for the credibility and generalizability of the findings. Additionally, the inclusion of a run-in phase, as implemented in the study, poses challenges in subject recruitment and retention. The substantial loss of eligible subjects (47.8%) before the trial even commenced raises concerns about the feasibility of this approach. Streamlining the study design by minimizing such barriers could improve the study's practicality and enhance the likelihood of achieving sufficient statistical power.

3. Tujuan Penelitian

Another point of consideration is the use of the laser-assisted wound measurement (LAWM) device for wound dimension measurement. While the device demonstrates validity in measuring wound area, it falls short in assessing wound depth, showing up to a 60% difference compared to ruler measurements. (Tan et al., 2023) (Davis et al., 2013) This limitation may introduce potential bias and affect the accuracy of the reported outcomes, questioning the reliability of the study's primary endpoint.

4. Manfaat Penelitian

In conclusion, while the study presents valuable insights into wound healing interventions, adherence to conventional analytical standards, careful consideration of measurement tools, and a comprehensive evaluation of wound outcomes are crucial for the advancement of the field. I encourage further discussions on these points and hope that future studies will address these concerns to strengthen the evidence base in wound healing research.

5. Hasil yang Diharapkan

No	Jenis Luaran				Indikator Capaian		
	Kategori	Sub Kategori	Wajib	Tambahan	TS ¹⁾	TS+1	TS+2
1	Artikel ilmiah dimuat di jurnal ²⁾	Internasional		√			
		Nasional terakreditasi			√		
		Nasional tidak terakreditasi					
2	Artikel ilmiah dimuat di prosiding ³⁾	Internasional					
		Nasional					
3	<i>Invited speaker</i> dalam temu ilmiah ⁴⁾	Internasional					
		Nasional					
4	Hak Kekayaan Intelektual (HKI) ⁶⁾	Paten					
		Paten sederhana					
		Hak cipta					
		Merek dagang					
		Rahasia dagang					
		Desain produk industry					

		Indikasi geografis					
		Perlindungan varietas tanaman					
		Perlindungan topografi sirkuit terpadu					
5	Tehnologi tepat guna ⁷⁾						
6	Model/Purwarupa/Desain/ Karya seni/ Rekayasa sosial ⁸⁾						
7	Buku ajar (ISBN)						
8	Tingkat kesiapan teknologi (TKT) ¹⁰⁾				1-2	3	

BAB II

RENSTRA DAN PETA JALAN PENELITIAN PERGURUAN TINGGI

Dalam penelitian ini, mengacu kepada RIP Universitas Esa Unggul yaitu Kualitas Kesehatan, Penyakit Tropis, Gizi & Obat-Obatan (*Health, Disease, Nutrition & Medicine*).

BAB III

TINJAUAN PUSTAKA DAN LANDASAN TEORI

1. Tinjauan Pustaka

I am writing in response to the article titled "A Novel Randomized Trial Protocol for Evaluating Wound Healing Interventions," published in *Advances in Wound Care*. I commend the authors for addressing crucial challenges in wound healing trials, particularly the limitations associated with dichotomous outcomes and difficulties in subject recruitment and follow-up. However, I would like to express some concerns and offer additional insights for consideration.

2. Tinjauan Teori

Firstly, the author acknowledges that the study was not powered, and comparisons were not made between randomized cohorts. These deviations from the standard analytical approach in clinical trials raise important questions about the robustness of the study's conclusions. As the randomized controlled trial is a cornerstone in evidence-based medicine, adherence to established analytical principles is paramount for the credibility and generalizability of the findings. Additionally, the inclusion of a run-in phase, as implemented in the study, poses challenges in subject recruitment and retention. The substantial loss of eligible subjects (47.8%) before the trial even commenced raises concerns about the feasibility of this approach. Streamlining the study design by minimizing such barriers could improve the study's practicality and enhance the likelihood of achieving sufficient statistical power.

Another point of consideration is the use of the laser-assisted wound measurement (LAWM) device for wound dimension measurement. While the device demonstrates validity in measuring wound area, it falls short in assessing wound depth, showing up to a 60% difference compared to ruler measurements. (Tan et al., 2023) (Davis et al., 2013) This limitation may introduce potential bias and affect the accuracy of the reported outcomes, questioning the reliability of the study's primary endpoint.

Moreover, the proposed outcome protocol seems to overlook essential wound healing aspects, such as wound bed quality and the presence of

tunnelling/undermining. These parameters play a crucial role in understanding the overall state of healing and should be considered in the evaluation of wound interventions. I propose the adoption of a wound scoring system tailored to the specific etiology, such as the DMIST Tool for diabetic foot ulcers, which already encompasses wound size and depth measurements along with other pertinent indicators.(Oe et al., 2020)

BAB IV

METODE PENELITIAN

1. Metode Penelitian

I am writing in response to the article titled "A Novel Randomized Trial Protocol for Evaluating Wound Healing Interventions," published in *Advances in Wound Care*. I commend the authors for addressing crucial challenges in wound healing trials, particularly the limitations associated with dichotomous outcomes and difficulties in subject recruitment and follow-up. However, I would like to express some concerns and offer additional insights for consideration.

2. Teknik Analisis Data

Firstly, the author acknowledges that the study was not powered, and comparisons were not made between randomized cohorts. These deviations from the standard analytical approach in clinical trials raise important questions about the robustness of the study's conclusions. As the randomized controlled trial is a cornerstone in evidence-based medicine, adherence to established analytical principles is paramount for the credibility and generalizability of the findings. Additionally, the inclusion of a run-in phase, as implemented in the study, poses challenges in subject recruitment and retention. The substantial loss of eligible subjects (47.8%) before the trial even commenced raises concerns about the feasibility of this approach. Streamlining the study design by minimizing such barriers could improve the study's practicality and enhance the likelihood of achieving sufficient statistical power.

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In summary, Shaabani et al. have developed an interesting PHD2 siRNA gold nanosystem as a pro-angiogenic therapeutic. Evaluation of sustained activity in inflammatory conditions, comparisons to miRNA-based approaches, benchmarking to other nanocarriers, and in-depth in vivo biocompatibility studies would strengthen conclusions regarding real-world efficacy and safety. I look forward to seeing this work address these gaps while evolving into a combination treatment approach optimized for the complex diabetic wound microenvironment.

BAB V

HASIL PENELITIAN

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BAB VI

PEMBAHASAN

Firstly, the author acknowledges that the study was not powered, and comparisons were not made between randomized cohorts. These deviations from the standard analytical approach in clinical trials raise important questions about the robustness of the study's conclusions. As the randomized controlled trial is a cornerstone in evidence-based medicine, adherence to established analytical principles is paramount for the credibility and generalizability of the findings. Additionally, the inclusion of a run-in phase, as implemented in the study, poses challenges in subject recruitment and retention. The substantial loss of eligible subjects (47.8%) before the trial even commenced raises concerns about the feasibility of this approach. Streamlining the study design by minimizing such barriers could improve the study's practicality and enhance the likelihood of achieving sufficient statistical power.

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BAB VII

KESIMPULAN DAN SARAN

A. KESIMPULAN

In conclusion, while the study presents valuable insights into wound healing interventions, adherence to conventional analytical standards, careful consideration of measurement tools, and a comprehensive evaluation of wound outcomes are crucial for the advancement of the field. I encourage further discussions on these points and hope that future studies will address these concerns to strengthen the evidence base in wound healing research.

BAB VIII

BIAYA DAN JADWAL PENELITIAN

A. Anggaran Biaya

A. Jadwal Penelitian

No	Jenis Kegiatan	Bulan ke-											
		1	2	3	4	5	6	7	8	9	10	11	12
1													
2													
3													
4													
6													
7													
8	Pembuatan laporan												
9	Seminar												
10	Publikasi												

DAFTAR PUSTAKA

- Davis, K. E., Constantine, F. C., MacAslan, E. C., Bills, J. D., Noble, D. L., & Lavery, L. A. (2013). Validation of a Laser-Assisted Wound Measurement Device for Measuring Wound Volume. *Journal of Diabetes Science and Technology*, 7(5), 1161–1166. <https://doi.org/10.1177/193229681300700508>
- Oe, M., Yotsu, R. R., Arisandi, D., Suriadi, Sakai, Y., Imran, Takehara, K., Nakagami, G., Tamaki, T., Sugama, J., & Sanada, H. (2020). Validity of DMIST for monitoring healing of diabetic foot ulcers. *Wound Repair and Regeneration*, 28(4), 539–546. <https://doi.org/10.1111/wrr.12816>
- Tan, P., Basonbul, R. A., Lim, J., & Moiemmen, N. (2023). Performance of portable objective wound assessment tools: a systematic review. *Journal of Wound Care*, 32(2), 74–82. <https://doi.org/10.12968/jowc.2023.32.2.74>

Lampiran 1. Surat Pernyataan Ketua Pelaksana

Surat Pernyataan Ketua Pelaksana Penelitian

Yang bertadatangan di bawah ini:

Nama : Adam Astrada, Ns., MHS, CNS, DHSc., FACCWS
NIDN/NIK : 1101059201
Fakultas/ Prodi : Ilmu-Ilmu Kesehatan
Jabatan fungsional : Lektor (200)

Dengan ini saya menyatakan bahwa proposal program penelitian yang diajukan dengan judul:

“Re: “A Novel Randomized Trial Protocol for Evaluating Wound Healing Interventions” by Bull et al.”

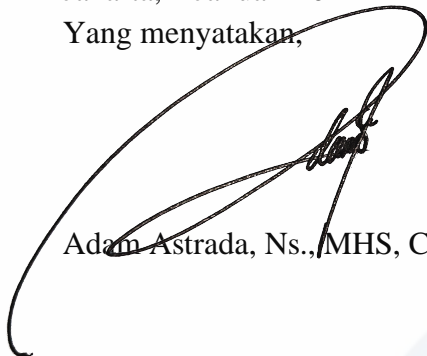
Yang saya usulkan dalam skema penelitian mandiri tahun 2024 bersifat original dan belum pernah dibiayai oleh lembaga/ sumber dana lain.

Bilamana diketahui dikemudian hari adanya indikasi ketidakjujuran/ itikad kurang baik sebagaimana dimaksud di atas, maka kegiatan ini dibatalkan dan saya bersedia mengembalikan dana yang telah diterima kepada pihak Universitas Esa Unggul melalui LPPM.

Demikian pernyataan ini dibuat dengan sesungguhnya dan dengan sebenar-benarnya.

Jakarta, 1 Januari 2024

Yang menyatakan,



Adam Astrada, Ns., MHS, CNS, DHSc., FACCWS

Lampiran 2. Biodata Pengusul dan Anggota

Biodata Pengusul