Study Title: Graft of Autologous minimally manipulated homologous adipose (AMHAT) for Treatment of chronic wound, DFU

Short title: AMHAT trial

Phase of the trial: Phase II

CTA Number: ET-CT-0040

Protocol No. 001

Version No.8 **Date:** October 30, 2023

National Principal Investigator (NPI): Ahmed Raja

Trial Site: Tikur Anbessa Specialized Hospital, College of Health Science, Addis Ababa

Sponsor: ROKIT Health care, Inc

Ethics Approval date: September 8, 2023

Submission Date to EFDA: October 30, 2023

EFDA Status of trial (Approval or Rejection): Authorized **Date:** June 20, 2024

Study Rationale

Diabetic foot ulcers (DFUs) are a significant public health concern in Ethiopia, with a prevalence rate of 12.98% among diabetic patients. The highest prevalence is observed in Addis Ababa, with a rate of 19.31%. DFUs are one of the leading reasons for hospital admissions, amputations, and even death among diabetic patients in Ethiopia.

General objective / Study aims

- To evaluate the efficacy of AMHAT (autologous minimally manipulated homologous adipose tissue) in improving chronic wounds in diabetic foot ulcers.

Primary objectives

Objective: To evaluate the efficacy of AMHAT (autologous minimally manipulated homologous adipose tissue) in improving chronic wounds in diabetic foot ulcers.

Outcome measures/endpoint: Complete epithelialization of the wound after the treatment

Secondary Objectives and Outcome Measures

Objective: To evaluate the efficacy of AMHAT (autologous minimally manipulated homologous adipose tissue) in improving chronic wounds in diabetic foot ulcers.

Outcome measures:

- Wound size and/or volume reduction
- Assessment of Wagner classification
- Time to Healing

Study Design

Phase II clinical trial (single-arm, pilot study)

Study Population

Type I or Type II diabetes patients with DFU

Eligibility Criteria

Inclusion Criteria:

- Patients over 18 years old
- Patients who have Type I or Type II diabetes
- Patients with ulcers of the lower extremities
- Patients whose transcutaneous oxygen pressure is over 30 mmHg or whose foot pulse is detected by the Doppler test
- Patients who are able and willing to provide consent and agree to comply with study procedures and follow-up evaluations.

Exclusion criteria:

- Patients who have an ulcer located over a Charcot deformity.
- Patients showing clinical signs of inflammation or infection in the ulcer area
- Patients who have been diagnosed with a malignant tumor.
- Patients with a history of participating in another clinical study within 4 weeks.
- Patients taking corticosteroids, immunosuppressive, or cytotoxic agents.
- Patients who are pregnant or breastfeeding
- Patients who are unsuitable to participate in the clinical trial according to the investigators.

Study Duration

four months

Investigational Medicinal Product

Formulation: N/A

Dose: N/A

Route of administration: N/A

Intervention

Hyper-personalized Skin Regeneration Platform (1 Dr. INVIVO and 20 Dr. INVIVO AI Regen KIT)

Sample size

Ten participants

Evaluator's Risk/Benefit Assessment:

Improved skin texture and color with risk of possible pain, bruising, numbness, bleeding, allergic reaction, and infection. Relatively, the risk is less than skin graft used for this type of wound.