Trial Description

Title

A RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, DOSE-RANGING, MULTICENTER, PHASE IIB CLINICAL TRIAL TO INVESTIGATE THE EFFICACY AND SAFETY OF ALLO-APZ2-CVU ON WOUND HEALING OF THERAPY-RESISTANT CHRONIC VENOUS ULCER (CVU)

Trial Acronym

allo-APZ2-CVU-IIb

URL of the trial

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Brief Summary in Lay Language

The objective of this clinical trial is to assess the efficacy (by monitoring wound closure) and safety (by monitoring adverse events [AEs]) of three different doses of the investigational medicinal product (IMP) allo-APZ2-CVU when administered topically to the target wounds of patients with CVU compared to placebo.

Brief Summary in Scientific Language

This is a randomised, placebo-controlled, double-blind, multicentre phase IIb clinical trial to determine the dose and investigate the efficacy and safety of the IMP allo-APZ2-CVU to promote wound healing in patients with therapy-resistant CVU.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00026609**
- Date of Registration in DRKS: **2021/09/15**
- Date of Registration in Partner Registry or other Primary Registry: **2021/07/21**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **291/20_ff , Ethik-Kommission der Medizinischen Fakultät der Universität Würzburg**

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2020-004960-24**
- Primary Registry-ID: **NCT04971161 (ClinicalTrials.gov)**

Health condition or Problem studied

- ICD10: **I87.21 - [generalization I87.2: Venous insufficiency (chronic)(peripheral)]**

Interventions/Observational Groups

- Arm 1: **allo-APZ2-CVU (dose group 1: 1 x 10e6 cells/cm²)**
- Arm 2: **allo-APZ2-CVU (dose group 2: 3 x 10e6 cells/cm²)**
- Arm 3: **allo-APZ2-CVU (dose group 3: 6 x 10e6 cells/cm²)**
- Arm 4: **Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IIb**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor**

Control: **Placebo**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **IIb**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Complete wound closure at Week 18 already persisting for at least two weeks

Assessment of adverse event (AE)

Secondary Outcome

- Wound size change in percent at each post-baseline follow-up visit;
- Time to complete wound closure;
- Complete wound closures at each post-baseline follow-up visit;
- Duration of wound closure;
- Recurrence of the wound;
- Quality of wound healing at each post-baseline follow-up visit;
- Assessment of Quality of Life using the W-QoL questionnaire at V8, V11 and V14;
- Pain assessment as per numerical rating scale on each post-baseline efficacy folow-up visit
- Physical examination and vital signs at V14.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Dermatologie und Allergologie , Augsburg**
- Medical Center **Fachklinik Bad Bentheim, Dermatologische Ambulanz, Bad Bentheim**
- Medical Center **Franziskus-Krankenhaus Berlin, Klinik für Innere Medizin, Angiologie und Diabetologie, Berlin**
- Doctor's Practice **Braunschweig**
- University Medical Center **Medizinische Klinik und Poliklinik III Angiologie und Gefäßzentrum, Dresden**
- University Medical Center **Heinrich-Heine-Universität Düsseldorf, Klinik für Dermatologie, Düsseldorf**
- University Medical Center **Klinik für Dermatologie und Venerologie, Freiburg im Breisgau**
- Medical Center **Klinik für Chirurgie (Allgemein-, Viszeral- und Endokrine Chirurgie, Thorax-, Gefäß- und Endovaskuläre Chirurgie und Kinderchirurgie) , Gelsenkirchen**
- Medical Center **SRH Wald-Klinikum Gera GmbH, Zentrum für Klinische Studien, Gera**
- Doctor's Practice **Halle Saale**
- University Medical Center **Universitätsklinikum Hamburg- Eppendorf, Institut für Versorgungsforschung in der Dermatologie und bei Pflegeberufen (IVDP), Hamburg**
- Doctor's Practice **Hanau**
- Medical Center **SRH Klinikum Karlsbad- Langensteinbach GmbH, Interdisziplinäres Gefäßzentrum Innere Medizin, Karlsbad-Langensteinbach**
- Medical Center **Medizinisches Versorgungszentrum DermaKiel GmbH, Kiel**
- Medical Center **Helios Klinikum Krefeld, Klinik für Dermatologie und Venerologie, Krefeld**
- Doctor's Practice **Langenau**
- other **medamed GmbH, Studienambulanz Leipzig, Leipzig**
- other **Beldio Research GmbH, Memmingen**
- Doctor's Practice **München**
- University Medical Center **Klinik für Hautkrankheiten, Allgemeine Dermatologie und Venerologie, Münster**
- Medical Center **Klinikum Nürnberg Nord, Klinik für Dermatologie, Nürnberg**
- Doctor's Practice **Potsdam**
- University Medical Center **Klinik und Poliklinik für Dermatologie und Venerologie, Rostock**
- Doctor's Practice **Stuttgart**
- University Medical Center **Universitäts-Hautklinik Tübingen, Tübingen**
- University Medical Center **Helios Universitätsklinikum Wuppertal, Zentrum für Dermatologie, Allergologie und Dermatochirurgie, Wuppertal**

- University Medical Center **Klinik und Poliklinik für Dermatologie, Venerologie und Allergologie, Würzburg**
- University Medical Center **Klinik und Poliklinik für Dermatologie, Venerologie, Leipzig**
- other **Klinische Forschung Dresden GmbH, Dresden**
- Medical Center **Helios Klinikum Emil von Behring GmbH, Berlin**
- Medical Center **Helios Klinikum Berlin-Buch, Berlin**
- University Medical Center **Klinik und Poliklinik für Dermatologie und Allergologie, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2021/08/18**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Male or female patients at least 18 years old;
Chronic venous leg ulcer (as defined by the current AWMF guidelines: therapy-resistant ulcer that shows no tendency to heal within 3 months despite of optimal phlebological therapies or has not fully healed within 12 months) at lower leg and/or ankle region and has not been present longer than 15 years, diagnosed by doppler or duplex sonography, ankle brachial index (ABI, 0.9-1.3), physical examination and dermatological review;
Wound size of target ulcer between 1 and 50 cm² measured by a standardized photography at the screening visits (Visit 1 and Visit 2);
If patients have 2 or more ulcers at the same extremity, the target ulcer has to be separated by a minimum bridge of 1 cm of epithelialized skin from other ulcers (the largest ulcer should be the target ulcer, if not decided otherwise at discretion of the investigator; the target ulcer is defined at Visit 1);
Body mass index between 15 and 50 kg/m²;
Patients understand the nature of the procedure and are providing written informed consent prior to any clinical trial procedure;
Women of childbearing potential must have a negative blood pregnancy test at Visit 1;
Women of childbearing potential and their partner must be willing to use highly effective contraceptive methods during the course of the clinical trial.

Exclusion criteria

Evidence of the ulcer extending to the underlying muscle, tendon, or bone;
Diabetes mellitus that has to be confirmed by blood test (Hemoglobin A1c >7.5%);
Peripheral Artery Disease including claudication with need of treatment;
Acute deep vein thrombosis (maximum 30 days from diagnosis) or a still untreated deep vein thrombosis;
Unable to tolerate leg ulcer compression bandage;
Infection of the target ulcer requiring treatment as judged clinically;
All diagnosed disorders, unrelated to CVU, that are influencing wound healing of the target wound at investigator's discretion;
Current use of medications that influence wound healing: systemic immunosuppressives, cytotoxic medicinal products, and systemic steroids (above Cushing-threshold level);

Patient who, in the opinion of the investigator, for any reason are unable or unwilling to complete the trial per protocol (e.g. alcohol or substance abuse, not mobile, short life expectancy) or there is evidence of any other medical condition (such as psychiatric illness, physical examination, or laboratory findings) that may interfere with the planned treatment, affect the patient's compliance, or place the patient at high risk of complications related to the treatment;
Any malignancy within the past 5 years, excluding successfully treated carcinoma in situ, basal cell carcinoma or squamous cell carcinoma of the skin without evidence of metastases;
Pregnant or lactating women;
Any known allergies to components of the IMP;
Prior surgical procedures such as bypass or mesh-graft treatment at target leg within 2 months prior to Visit 1 at target leg;
Patients with significant ulcer healing or wound size enlargement of more than 25% at Visit 2 compared to Visit 1;
Treatment of target ulcer with active wound care agents (e.g. Iruxol®N, silver dressings), which have not been paused 14 days before IMP application;
Current or previous (within 30 days of enrollment) treatment with another IMP, or participation and/or under follow-up in another clinical trial;
Previous participation in this clinical trial (except for screening failures due to an inclusion or exclusion criterion);
Employees of the sponsor, or employees or relatives of the investigator.

Addresses

■ **Primary Sponsor**

RHEACELL GmbH & Co. KG
Im Neuenheimer Feld 517
69120 Heidelberg
Germany

Telephone: **+49 6221 71833-0**
Fax: **[---]***
E-mail: **office at rheacell.com**
URL: **https://www.rheacell.com/**

■ **Contact for Scientific Queries**

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- **Collaborator, Other Address**

  FGK Clinical Research GmbH
  Heimeranstr. 35
  80339 München
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Collaborator, Other Address**

  TICEBA GmbH
  Im Neuenheimer Feld 517
  69120 Heidelberg
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  RHEACELL GmbH & Co. KG
  Mr.
  Im Neuenheimer Feld 517
  69120 Heidelberg
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***

Number of Participants in Germany after Recruiting complete: **[---]***

■ Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*