

Trial to Evaluate the Safety and Effectiveness of Treatment With COMS One Device in Subjects With Diabetic Foot Ulcers

NCT05758545

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| Status | RECRUITING |
| Phase | Not Applicable |
| Sponsor | Piomic Medical |
| Enrollment | 450 participants |

Key Eligibility Criteria

Inclusion (10)

- Subjects are male or female, e22 and d90 years of age
- Female subjects of childbearing potential must be willing to use acceptable methods of contraception (birth control pills, barriers, or abstinence) starting at screening and throughout the duration of their study participation.
- The participant (or LAR if applicable) must be able to understand and sign the informed consent form (ICF) and comply with requirements set in the protocol including trial visits, trial treatment and dressing regimens and compliance with required offloading device (if applicable)
- Type 1 or Type 2 diabetes mellitus
- Presence of one full-thickness DFU located at or below the malleoli (If the subject has more than one DFU that meets eligibility criteria, the investigator will designate one DFU as the target DFU to be treated in the trial)

... and 5 more (see full listing online)

Exclusion (20)

- Known pregnancy or lactating
- Active skin cancer, a history of skin cancer or any other localized cancer, precancerous lesions or large moles in the areas to be treated.
- Subject who is taking any medications the Investigator believes may interfere with healing of the target DFU
- Subject who is currently undergoing treatment for an active systemic infection, including osteomyelitis
- Wagner Grade 3, 4 or 5

... and 15 more (see full listing online)

Locations (30 total)

Titan Clinical Research, Mesa, Arizona, United States
Southern Arizona VA Health Care System, Tucson, Arizona, United States
Center for Clinical Research Inc., Castro Valley, California, United States

... and 27 more locations