Suprasorb®X+PHMB Pro vs Suprasorb®X+PHMB in Treatment of Infected Venous Leg Ulcers

NCT07211243

Status	RECRUITING
Phase	Not Applicable
Sponsor	Lohmann & Rauscher
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (5)

- Age e 18 years
- Infected* venous** leg ulcer
- Slightly to moderately exuding wound***
- Patient has signed informed consent
- as per CDC definition, also TILI score e 5 ** ABPI \> 0.8 and \< 1.2 *** patients with highly exuding wounds may be screened for a 7 days run-in period to receive superabsorbent dressing and monitored compression therapy and re-con-sidered for enrolment in case the exudation level decreases

Exclusion (5)

- Participation in other interventional clinical trial that could interfere with the present study within 4 weeks of the randomisation and during the whole duration of this study
- Wounds with exposed cartilage tissue (hyaline cartilage)
- Contraindications to compression therapy (e.g.: advanced peripheral ar-terial occlusive diseases, decompensated cardiac insufficiency, septic phlebitis, phlegmasia coerulea dolens, sensation disorders of the skin)
- Known allergy and/or hypersensitivity to any components of the study product or concomitant products (e.g. compression bandage)
- Any other medical condition, which, by opinion of the investigator, may have impact of the success of the study treatment and / or interpreta-tion of the study results.

Locations (9 total)

ClinicMed Daniluk, Nowak SpóBka Komandytowa OZRODEK LECZENIA RAN i OwrzodzeD, Bialystok, Poland
Centrum Medyczne Ultramed, Krakow, Poland
MelissaMed Poradnia Chirurgiczna, Lodz, Poland
... and 6 more locations