



Prospective controlled randomized trial on the effectiveness, quality of life and cost-effectiveness of the Blue Light Photobiomodulation treatment for leg ulcers.

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## STUDY DESIGN

- The clinical study aims to compare the healing rate between the control group, treated twice a week with standard of care (SoC) only, and the experimental group, treated once a week with Soc and Blue Light PBM over a follow-up of 16 weeks

### **Control Group**


Twice a week visit  
with  
SOC

**VS**

### **Treatment Group**

Once a week visit  
with  
SOC + EmoLED

- Blue Light treatment is performed for 60 seconds on the entire lesion's area with a portable, rechargeable medical device that uses Blue LEDs sources emitting in the 410-430 wavelength range with 120 mW/cm<sup>2</sup> power density.

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- The lesion size, the pain (VAS scale), quality of life as well as the direct (health and non-health) and indirect costs are prospectively collected.

- **PATIENTS: INCLUSION CRITERIA**

- Subjects suffering from venous and mixed skin ulcers;
- Presence of a lesion smaller than 100 cm<sup>2</sup> and shallower than 1 cm;
- Men and women  $\geq$  18 years old;
- The patient must be able to understand the aims of the clinical study and provide informed consent in writing;
- Chronicity of the lesion: at least 8 weeks.



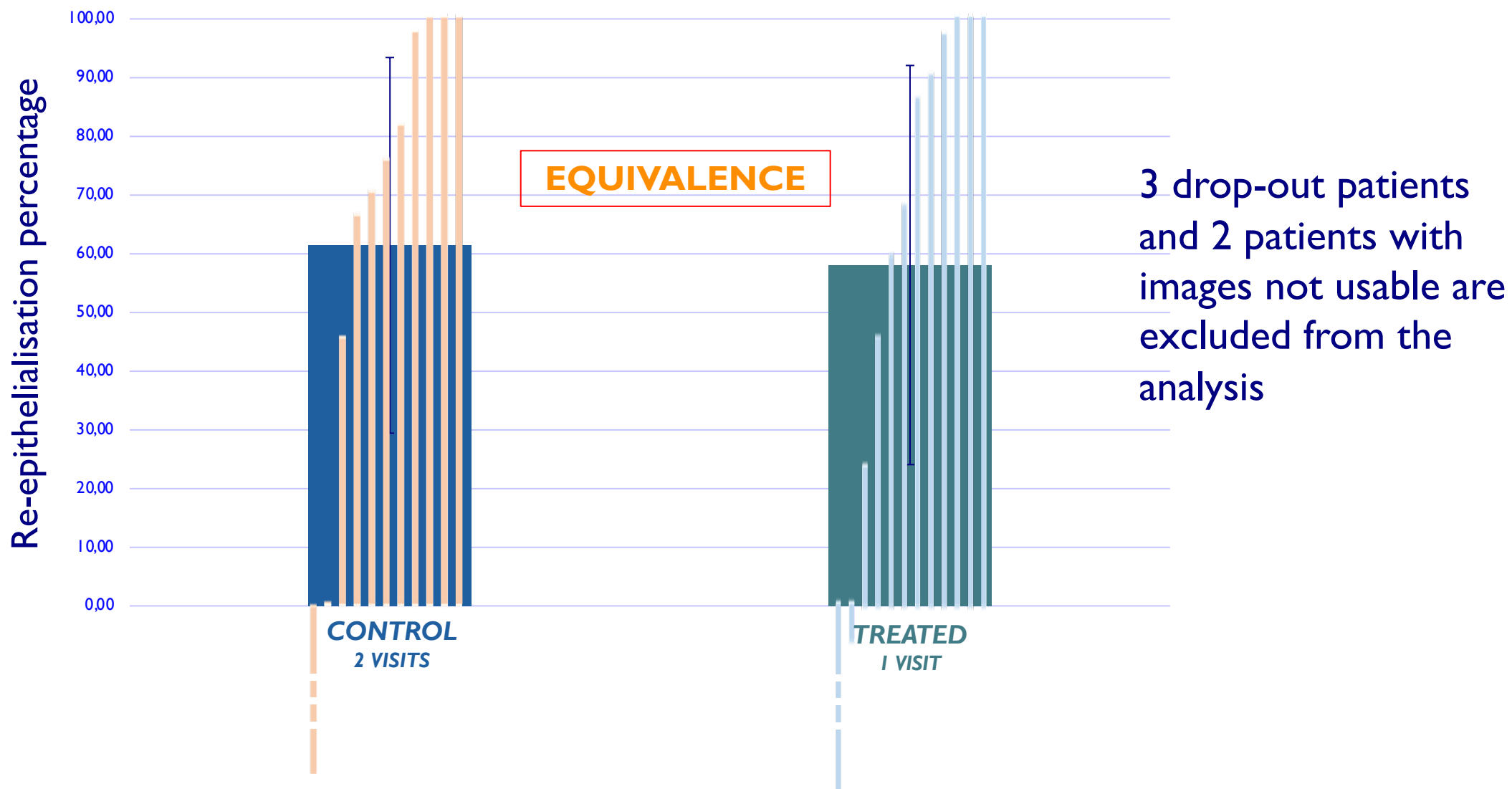
## CLINICAL RESULTS

Four facilities are involved and a total of 80 patients will be recruited.  
Only patients from our Center are considered for these results.

- 28 patients (21 female; 7 male). Treatment group: 14 patients. Control group: 14 patients.
- 3 drop-out (Control group), 2 not following protocol (Treatment group, included in the analysis)
- Median age: 77 years (51-96).
- Median ulcer duration: 13 months (2-56)
- Ulcers' etiology: only two mixed ulcers and 26 venous ulcers.
- Main comorbidities: arterial hypertension; diabetes; cardiopathy.



## Average re-epithelialisation ( $T_0 - T_{16}$ ) (data from *image analysis*\*)

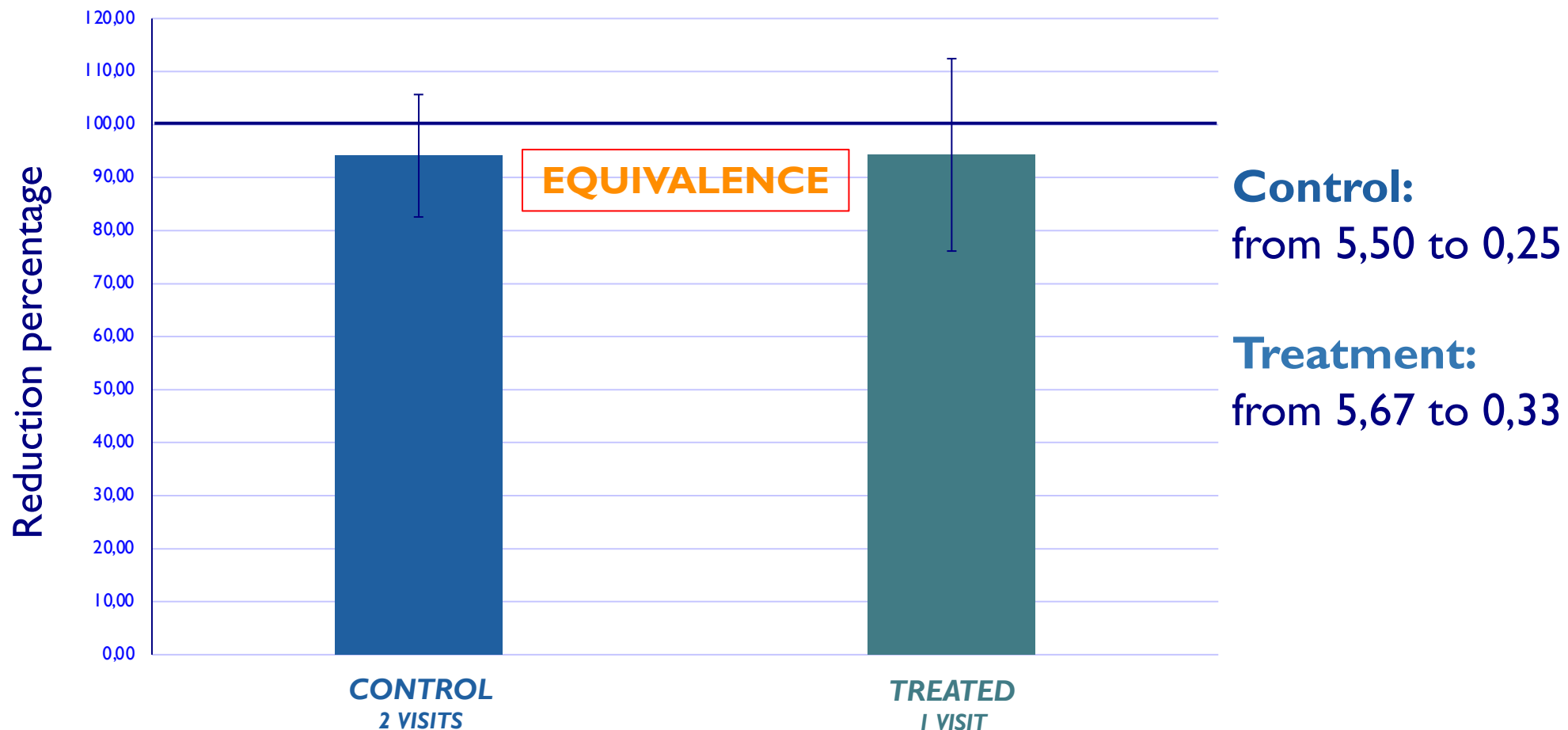


\* Performed by CNR-IFC Pisa, Institute of Clinical Physiology





## Average pain reduction ( $T_0 - T_{16}$ ) VAS scale (pain at $T_0 < 4$ )



Nine patients showed a pain value at  $T_0 < 4$ .

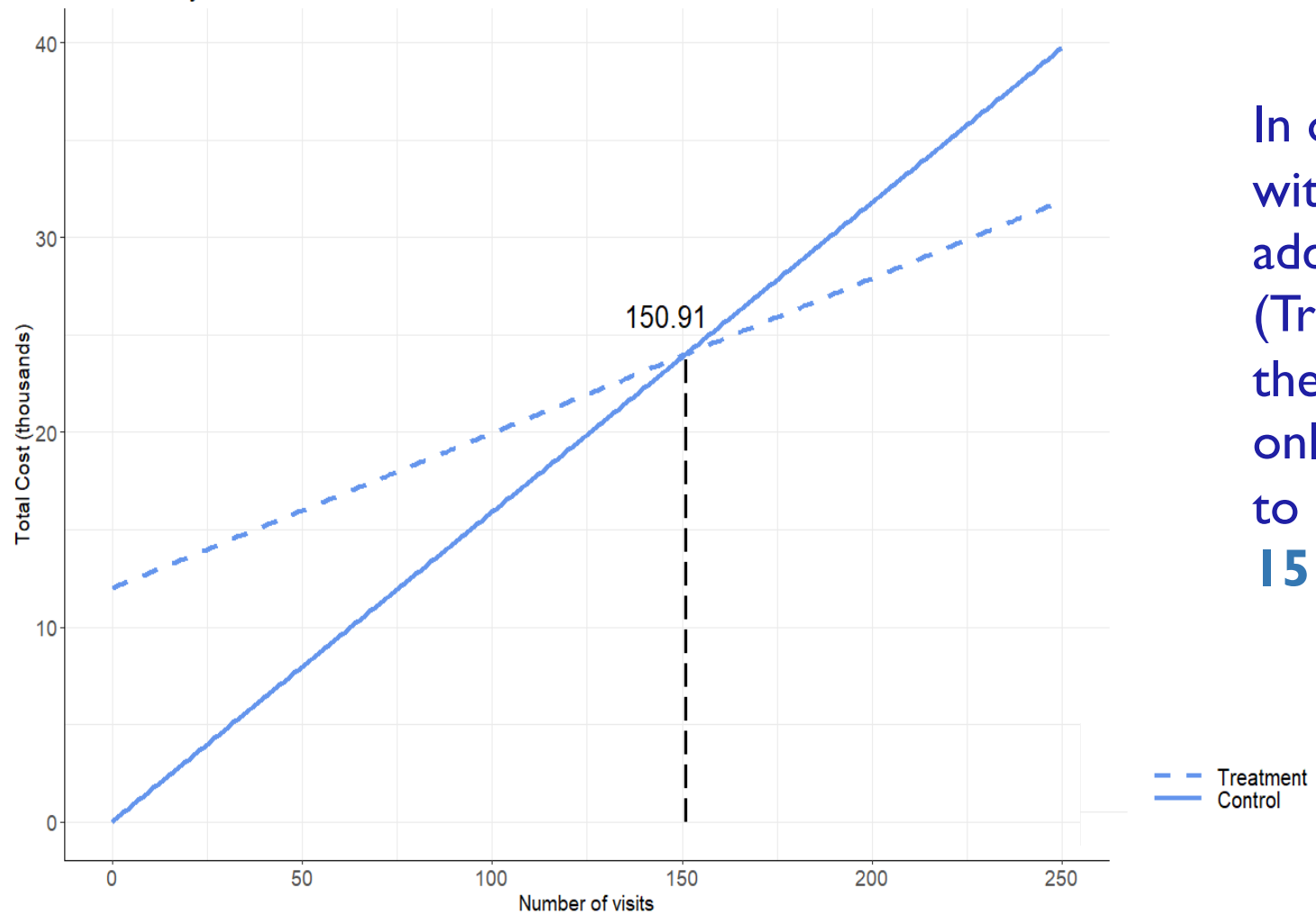




## ECONOMIC IMPACT (BASED ON DIRECT HEALTH COSTS)

Based on the following data, we have calculated the threshold value of the number of visits beyond which the use of Blue Light PBM in addition to standard of care is economically advantageous for our Center.

- Preliminary clinical results show that using Blue Light PBM we can halve the number of visits per patient while maintaining equivalent clinical results.
- The business model used for the Blue Light PBM medical device provides for an annual rental at a cost of 12,000.00 euros (all inclusive) and the unit cost per treatment decreases when the number of treated patients increases.
- The estimated direct cost (material and personnel) per visit at our Centre is 79.52 euros.



In our Center, treatment with Blue Light PBM in addition to standard therapy (Treatment), compared to the use of standard therapy only (Control), turned out to be advantageous after **151 visits**.

*Total direct cost trend by number of visits (treated vs control).*







## CONCLUSIONS

Based on the preliminary results of the ongoing study, the use of Blue Light PBM in addition to standard of care can halve the number of outpatient accesses, reducing advanced dressings' consumption and increasing the taking in charge of new patients by the wound clinic.

*The MD for photobiomodulation with blue light was provided by Emoled srl which is also sponsor of the clinical study.*

