SELECIONADO PARA PALESTRA

Study of the safety of topical application of bacterial nanocellulose membranes modified with Poly-L-Lysine-Cholesterol: protocol for phase I clinical trials

SGAWCM 2025 Experience
May 28th-30th Hybrid
São Paulo Brazil
SOBRATAFE
Centro de Convenções Rebouças

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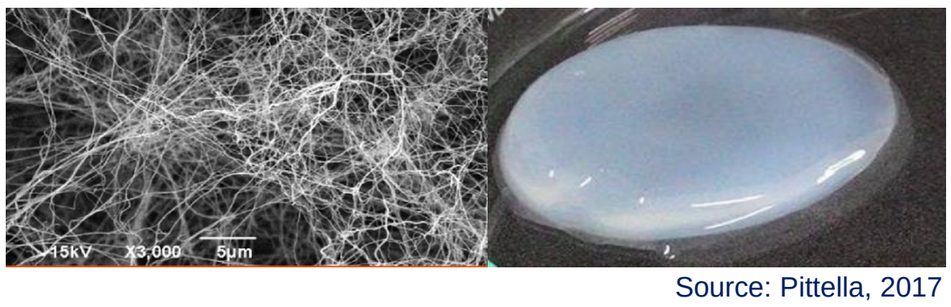
INTRODUCTION

- Wounds are characterized by loss of skin continuity and have become a major health problem. As a result, new materials have been created and studied to treat various injuries, such as Bacterial Nanocellulose (BNC).

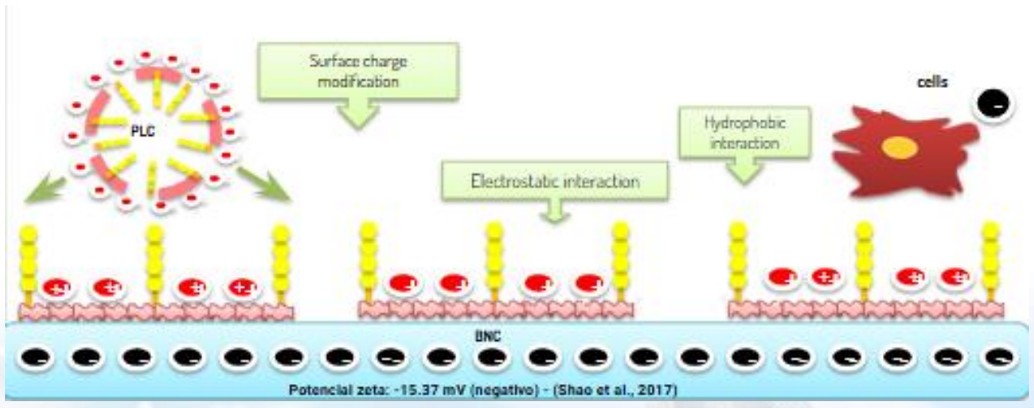
Microscopical and optical images of BNC



Source: Pittella, 2017

- BNC is a natural polymer, synthesized by the bacterium *Gluconacetobacter*, composed of hydrated nanocellulose fibrils. This hydrogel is an emerging biomaterial used for a wide range of biomedical applications.
- In an attempt to develop new strategies for tissue repair, it receives modifications on its surface, expanding its functions, one of which, is the adsorption of Poly-L-Lysine-Cholesterol (PLC).

Schematic structure of BNC-PLC



Source: Pittella, 2017

- BNC-PLC has undergone preclinical phases, showing promising results. However, in order to continue studies and future availability, it is necessary to carry out clinical trials.
- A clinical trial protocol is necessary for planning the conduct of the study, with an assessment of scientific, ethical and safety issues before the start of the study, in addition to its faithful reproduction and scientific rigor.

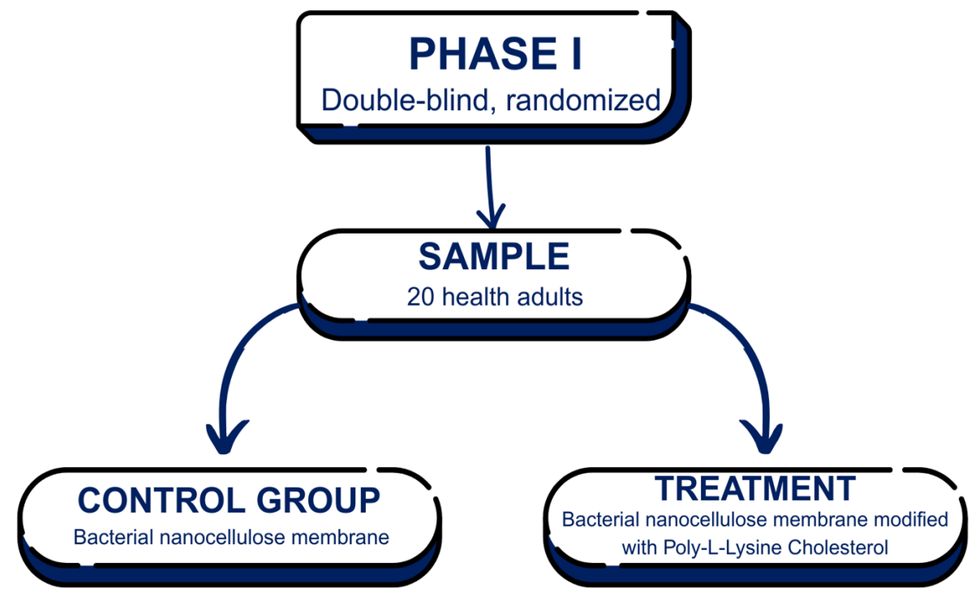
OBJECTIVE

To develop a protocol to study the safety of topical application of bacterial nanocellulose membranes modified with Poly-L-Lysine-Cholesterol.

METHOD

The protocol was developed based on the Standard Protocol Items Recommendations for Interventional Trials, known as SPIRIT statement (2013).

SPIRIT
Standard Protocol Items: Recommendations for Interventional Trials



Sign and symptoms of local allergic reaction and indications of inflammatory reaction, liver and kidney toxicity will be analyzed before and after application of the membranes.

RESULTS

- This work has made it possible to draw up a phase I clinical study protocol, the result of which is its own construction. It is hoped that it will serve as a support for conducting the study.
- It will define, among other important points, the procedures, interventions, primary outcome, secondary outcome, among other important points for the construction of the protocol.

CONCLUSION

- The protocol defines the items required to carry out the phase I clinical trial on the safety assessment of the topical application of BNC membranes modified with PLC in a safe and standardized manner.
- It also makes it easier to organize the data and the main interventions to be carried out so that the study can be conducted satisfactorily.
- As such, it is fundamental for carrying out the test and consequently for the next stages in the development of the new product and its implementation in the health area.
- Therefore generating benefits for society through its future availability on the market as an innovative therapeutic form for wounds.

I have no conflict of interest

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