Plan Overview

A Data Management Plan created using DMPTool

Title: Combined effects of Propanediol, Butylene Glycol and Glycerol on skin barrier function and skin hydration

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Template: UNICAMP GENERIC: Aplicável a todas as áreas

Project abstract:

The aim of this study was to evaluate the effect of humectants used in cosmetic products in improving skin hydration and the efficiency of the skin barrier.

The effect of Propanediol in different concentrations (5%, 10% and 15%), applied alone or combined with Butylene glycol (5%) and/or Glycerol (5%), was assessed through skin capacitance measurements using the Corneometer® 825 probe and through transepidermal water loss (TEWL) measurements using the Tewameter® TM300 probe.

Capacitance and TEWL measurements were performed at baseline, after 15 minutes, 2 and 8 hours of products application.

The results obtained in this study can be used in the development of new formulations and to conceive prescription forms that aim for better clinical answers to repair and hydrate the skin.

Start date: 02-09-2021

End date: 08-09-2021

Last modified: 03-14-2022

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Combined effects of Propanediol, Butylene Glycol and Glycerol on skin barrier function and skin hydration

Descrição dos Dados e Metadados

Quais serão os dados coletados?
During the study, measurements of skin capacitance, given in arbitrary units, and measurements of transepidermal water loss (TEWL), given in g/h/m², were obtained from healthy female subjects.
Capacitance and TEWL measurements were obtained at baseline (prior to application of humectants), after 15 minutes, 2 and 8 hours of application. The capacitance and TEWL measurements of the investigated products were performed on the volar face of the forearm of the subjects.
The digital data generated during the project are Excel spreadsheets with capacitance values that were measured using the Corneometer® 825 probe and TEWL values that were measured using the Tewameter® TM300 probe, coupled to the Courage & Khaska MPA-5 equipment.

Que metadados serão anotados e qual padrão será seguido?
Data will be stored in XLS/XLSX format (spreadsheets) and can be accessed and manipulated using Microsoft Excel or similar software.

Quais são as questões legais e éticas associadas aos dados e relevantes a este projeto?
Raw data may only be shared with the authorization of the Responsible Investigator, upon request made by the interested party.
Data that can identify research participants included in the study will be anonymized.
The completed and signed informed consent forms were filed in the study brochure and will be available for consultation by the responsible researchers for a minimum period of five years and a maximum of ten years after the end of the clinical study.
The subjects received the guarantee, by signing the informed consent, that their identity will be kept confidential and that no information will be given to other people who are not part of the research team. When disclosing the results of the study, the names of subjects will not be mentioned and any other information that could identify them will be kept anonymous and will never be disclosed.

Quais serão as políticas a serem utilizadas para o compartilhamento de dados?
The study protocol, under the CAAE number of 29880820.2.0000.5404, was approved by the Ethics in Research Committee (CEP) according to report number 4.018.746. The study was conducted in accordance with the Good Clinical Practice and the Declaration of Helsinki. All subjects provided written informed consent.

Aspects Legais e Facilidade de Acesso aos Dados

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Quais serão as políticas a serem utilizadas para o compartilhamento de dados?
The data will be stored in Research Data Repository of Unicamp (REDU). Data from 30 subjects with healthy skin, that were collected in a clinical study carried out to evaluated the effect of humectants used in cosmetic products in improving skin hydration and skin barrier efficiency, from capacitance measurements obtained with the Corneometer probe 825 and TEWL measurements obtained with the Tewameter® TM300 probe, respectively.

Gestão de Dados e Armazenamento

Em que formatos serão armazenados os arquivos resultantes da pesquisa em questão? Que software poderá ser utilizado para a manipulação de cada um dos formatos listados?
The data will be stored in an indefinite period of time and not less than five years.

Como e onde estes arquivos serão mantidos? Por quanto tempo ocorrerá esta preservação? Como será realizado o backup destes dados?

Keywords: TEWL, Capacitance, skin hydration, skin barrier, humectants.
Year of publication: 2022
URL: http://repositorio.unicamp.br/