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Palatability of different urea oral formulations used in the treatment of low blood sodium levels

Submission date
23/06/2023

Recruitment status
No longer recruiting

Registration date
26/06/2023

Overall study status
Completed

Last Edited
07/12/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aim
Hyponatremia (when the sodium level in the blood is below normal) is the most common disorder of electrolytes encountered in clinical practice. HN is associated with illness and death, so it is important to identify treatments for these patients. Oral urea represents an effective, safe, and well-tolerated approach to the management of chronic hyponatremia. Oral urea is commonly prepared as a galenic formulation that is usually associated with distaste problems. The aim of this study is to compare the palatability of two different urea formulations: a commercial urea formulation and a galenic one.

Who can participate?
Healthy volunteers aged 50 to 60 years old

What does the study involve?
Participants are randomly allocated to consume the urea formulation A or B twice a day away from meals, solubilizing the products in 125 ml of water (T0). After a 3-day break, participants swap over and consume the other formulation twice a day away from meals. After the consumption of products, both in the morning and in the evening, participants complete a specific questionnaire to evaluate their palatability.

What are the possible benefits and risks of participating?
The study aims to identify a urea formulation with good taste to improve adherence to the therapy in patients with chronic hyponatremia. No specific risks are expected.

Where is the study run from?
Eurofins Cosmetics & Personal Care Italy S.r.l (Italy)

When is the study starting and how long is it expected to run for?
April 2023 to May 2023

Who is funding the study?
Difa Cooper SPA (Italy)

Who is the main contact?
Dr Massimo Milani, massimo.milani@difacooper.com

Contact information

Type(s)
Public

Contact name
Dr Massimo Milani

ORCID ID
https://orcid.org/0000-0001-7559-1202

Contact details
Via Milano 160
Caronno Pertusella
Italy
21042
+39 (0)29659031
massimo.milani@difacooper.com

Type(s)
Public

Contact name
Dr Francesca Colombo

ORCID ID
https://orcid.org/0000-0002-8099-0192

Contact details
Via Milano 160
Caronno Pertusella
Italy
21042
+39 (0)29659031
francesca.colombo@difacooper.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CLAB/01/2023

Study information

Scientific Title
Palatability of two different formulations of urea for the treatment of hyponatremia: a double-blind, cross-over study

Acronym
UrHyp

Study objectives
The aim of this study was to evaluate, in a panel of healthy human subjects, the palatability of two different urea formulations: a commercial formulation (Food for Special Medical Purposes) was compared to a galenic one.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/04/2023, Internal Revision Committee of Cosmetics & Personal Care Italy Srl (via Bruno Buozzi, 2, Vimodrone (MI), 20055, Italy; +39 (0)2 25 071 51; InfoCosme@eurofins.com), ref: STUN723AA0075

Study design
Monocentric randomized double-blind two-arm cross over clinical trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Hyponatremia

Interventions
The study evaluated the palatability of two urea formulations and was divided into two cross-over phases. Each participant consumed formulation A or formulation B twice a day away from meals, solubilizing the products in 125 mL of water (T0). After 3 days of wash-out (T1-T3, discontinuation of product intake), the formulations were cross-over and consumed twice a day away from meals (T4).

Participants were randomized to consume a commercial urea formulation (Food for Special Medical Purposes, UREAL NM, Cantabria Labs, Difa Cooper, Caronno Pertusella, Italy) and a galenic urea formulation. The randomization list was generated by a dedicated computer program. The commercial urea formulation contains urea, flavouring, dextrose, sweeteners: sucralose, aspartame, acidifier: citric acid; the galenic formulation contains only urea. Participants consumed 7 g of each product (formulation A or formulation B) twice daily, solubilized in 125 ml of water.

Intervention Type

Other

Primary outcome(s)
Product palatability measured using a questionnaire modified from IJpma et al (2016) filled in by the test subjects after each intake on T0 and T4

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
02/05/2023

Eligibility

Key inclusion criteria
1. Age 50-60 years
2. 50% female and 50% male
3. Non-smokers

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Upper age limit
60 years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Personal history of taste disorders
2. Presence of conditions capable of altering the sense of taste

Date of first enrolment
27/04/2023

Date of final enrolment
27/04/2023

Locations

Countries of recruitment
Italy

Study participating centre
Cosmetics & Personal Care Italy Srl
via Bruno Buozzi, 2
Vimodrone (MI)
Italy
20055

Sponsor information

Organisation
Difa Cooper (Italy)

ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Industry

Funder Name
Difa Cooper

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during the current study will be available upon request from Dr Francesca Colombo (francesca.colombo@difacooper.com). The final study report and raw data of all participants could be available on request.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	09/11/2023	07/12/2023	Yes	No