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An investigation to determine the absorption of magnesium through the skin using a magnesium cream

Submission date
14/10/2016

Recruitment status
No longer recruiting

Registration date
21/10/2016

Overall study status
Completed

Last Edited
08/11/2023

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Magnesium is needed by the human body in small amounts for good health and functioning. It has been found to improve blood pressure and general well-being. It is often taken as a supplement as it may be lacking in the diet. More recently magnesium has been added to body creams and oils in order to increase magnesium levels in the body and as an alternative to taking a tablet. However, it is not known whether the magnesium in the cream is absorbed into the body. The aim of this study is to determine whether magnesium in a cream can be absorbed through the skin by assessing blood and urine levels of magnesium.

Who can participate?
Healthy men and women aged 18-60 years

What does the study involve?
Participants are randomly allocated to one of two groups. Those in one group apply a cream containing magnesium. Those in the other group apply a cream that does not contain magnesium. The cream is applied every day for 14 days. Before the participants start to apply the cream they provide a blood sample to check their magnesium levels, along with urine samples to check the amount of magnesium in their urine. Participants also had to record the food they ate for 4 days and complete two simple questionnaires on how they felt and their general well-being. After applying the cream for 14 days, blood and urine samples are collected and tested again along with a further 4 days of food diaries and a repeat of the two simple questionnaires. Absorption of the cream could then be measured as well as any changes in their general well-being.

What are the possible benefits and risks of participating?
Participants may benefit from the positive effects of the magnesium cream (e.g., improved well-being). They also have their diet analysed. There are no risks associated with the study apart from those associated with normal blood collection.

Where is the study run from?
University of Hertfordshire (UK)

When is the study starting and how long is it expected to run for?
April 2014 to February 2015

Who is funding the study?
University of Hertfordshire (UK)

Who is the main contact?
Ms Lindsy Kass
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Contact information

Type(s)
Scientific

Contact name
Ms Lindsy Kass

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
LMS SF UH 00057

Study information

Scientific Title
Absorption of transdermal magnesium cream in humans via serum and urinary analysis

Study objectives

Magnesium can be absorbed through a transdermal cream, increasing serum levels and urinary excretion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Hertfordshire Health and Human Sciences Ethics Board, 14/04/2014, ref: LMS SF UH 00057

Study design
Single-blind single-centre parallel-designed placebo-controlled randomized trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Absorption of magnesium through a transdermal cream

Interventions
The participants were randomly assigned to one of the following two treatments:
1. The magnesium cream (intervention)
2. An aqueous cream (placebo)

Thirty pieces of paper were placed into a bag, 15 stating Mg and 15 stating placebo. On recruitment of a participant onto the trial an independent colleague pulled one of the pieces of paper from the bag and the participant was assigned to that group.

Participants administered the cream for 14 days at a dose of 2 x 5ml/day (a measured spoon being provided) containing either 56mg magnesium or placebo. The cream was rubbed into the torso and legs. Food diaries were collected for 4 days at the beginning of the trial and 4 days at the end of the trial and analysed for dietary magnesium intake. A health questionnaire was administered pre and post intervention to determine feelings of well being and general health.

Intervention Type
Supplement

Primary outcome(s)
1. Serum magnesium levels, measured through venepuncture blood collection at baseline and again within the last 2 days of the intervention.
2. Urinary excretion, measured using 24h collection and analysed at baseline and again within the last 2 days of the intervention

Key secondary outcome(s))
1. Habitual dietary magnesium intake, assessed via 2 x 4 day food diaries, of which 4 days were collected at the beginning of the trial and a further 4 days at the end of the trial
2. General feeling of well being, assessed using a EQ-5D Health survey and short questionnaire before and after the intervention

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Males and females
2. Aged 18-60 years
3. In good health
4. Not taking any medication (with the exception of the contraceptive pill and asthma inhalers)
5. Not taking a magnesium supplement in any form
6. Not having a blood-borne disease

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Younger than 18 years and older than 60 years
2. Not in good health
3. Taking medication (with the exception of the contraceptive pill and asthma inhalers)
4. Taking a magnesium supplement
5. Having a blood-borne disease

Date of first enrolment
23/10/2014

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Hertfordshire
College Lane
Hatfield
United Kingdom
AL10 9AB

Sponsor information

Organisation
University of Hertfordshire

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
University/education

Funder Name
University of Hertfordshire

Alternative Name(s)
UH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Ms Lindsy Kass (l.s.kass@herts.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/04/2017		Yes	No
Dataset		12/04/2017	08/11/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (other)		12/04/2017	08/11/2023	No	No