ISRCTN18054903 https://doi.org/10.1186/ISRCTN18054903

Time variability of flush-onset and flush tolerabililty in individuals given 500 mg niacin (nicotinic acid): a randomised controlled trial

Submission date	Recruitment status
14/11/2002	No longer recruiting
Registration date	**Overall study status**
14/11/2002	Completed
Last Edited	**Condition category**
05/09/2007	Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cutaneous reactions (flushing)

Interventions
Participants divided into two groups:
1. Verum group takes one 500 mg tablet of niacin
2. The control group takes a placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Niacin (nicotinic acid)

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

Completion date
31/12/2002

Eligibility

Key inclusion criteria
1. Age range 20 - 60 years
2. Currently enrolled at The Canadian College of Naturopathic Medicine (CCNM)
3. Not currently taking any prescribed medication that influences gastric acid secretion
4. Does not have current or past liver disease (e.g., chronic active hepatitis, cirrhosis, etc)
5. Does not have current or past history of gout or active gout
6. Does not have current or past gastrointestinal disease (e.g., peptic ulcer disease, gastric cancer, etc)
7. Does not have current or past diagnosis of diabetes mellitus
8. Does not have a past episode or history of intolerance to niacin
9. Was able to complete the intake form

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
68

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2002

Locations

Countries of recruitment

Canada

Study participating centre
Director of Research
North York, Ontario
Canada
M2K 1E2

Sponsor information

Organisation
Canadian College of Naturopathic Medicine (Canada)

Sponsor details
1255 Sheppard Ave East
North York, Ontario
Canada
M2K 1E2

Sponsor type
University/education

Website
http://www.ccnm.edu/

ROR
https://ror.org/03pjwtr87

Funder(s)

Funder type
University/education

Funder Name
Canadian College of Naturopathic Medicine (Canada)

Funder Name
Jamieson Laboratories donated the study drug and placebo. They had no role in study design, data analysis, and they have not received the study results.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	13/11/2003		Yes	No