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

Submission date	Recruitment status	Prospectively registered	
14/11/2002	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
14/11/2002	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
05/09/2007	Skin and Connective Tissue Diseases		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Edward Mills

Contact details

Director of Research
Canadian College of Naturopathic Medicine
1255 Sheppard Ave East
North York, Ontario
Canada
M2K 1E2
+1 416 498 1255 ext 324
emills@ccnm.edu

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

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