

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

Submission date 14/11/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/11/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/09/2007	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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