

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

☐ Prospectively registered

☐ Protocol

Registration date

14/11/2002

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

05/09/2007

Condition category

Skin and Connective Tissue Diseases

☐ 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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Contact details

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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

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Sponsor information

Organisation

Canadian College of Naturopathic Medicine (Canada)

Sponsor details

1255 Sheppard Ave East

North York, Ontario

Canada

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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