Determining if ingestion of silybum marianum (milk thistle) influences the metabolisation of indinavir in healthy subjects: a randomised controlled phase I study

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
06/11/2002		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/11/2002	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
09/10/2007	Other			

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

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Drug interactions

Interventions

Milk thistle (silybum marianum) and indinavir.

Twenty-four healthy male participants: All individuals will receive a HIV test and Liver Function Tests (LFTs - aspartate aminotransferase [AST], alanine aminotransferase [ALT], gamma-glutamyl transferase [GGT]) to exclude HIV and liver disease, and also a Complete Blood Count (CBC).

Subjects are requested to discontinue all medications, alcohol, caffeine, nicotine and other known CYP 3A4 inducers and inhibitors. Informed consent will be obtained from all participants.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Milk thistle, indinavir

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2003

Completion date

31/12/2005

Eligibility

Key inclusion criteria

- 1. Documented Enzyme-Linked Immunosorbent Assay (ELISA) and Western Blot results negative for Human Immunodeficiency Virus (HIV)
- 2. Aged 18 35 years
- 3. Sex male, race Caucasian, and normal findings of laboratory and physical examinations

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

24

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Canada

Study participating centre
Director of Research, Canadian College of Naturopathic Medicine
North York, Ontario
Canada
M2K 1E2

Sponsor information

Organisation

Ontario HIV Treatment Network

Sponsor details

1300 Yonge Street
Suite 308
Toronto, Ontario
Canada
M4T 1X3
+1 416 642 6486
Toll Free: +1 877 743 6486
info@ohtn.on.ca

Sponsor type

Not defined

ROR

https://ror.org/03hgdjp72

Funder(s)

Funder type

Research organisation

Funder Name

Ontario HIV Treatment Network (Canada)

Alternative Name(s)

The Ontario Hiv Treatment Network, OHTN

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Canada

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	01/03/2005		Yes	No