

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

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

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

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

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

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, The OHTN, the_ohtn, OntarioHIVTreatment, Ontario HIV Treatment Network (OHTN) | Toronto ON, OHTN

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/03/2005		Yes	No