ISRCTN78545137 https://doi.org/10.1186/ISRCTN78545137

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

Registration date
06/11/2002

Overall study status
Completed

Last Edited
09/10/2007

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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
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Sponsor information

Organisation
Ontario HIV Treatment Network

Sponsor details
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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