

A randomised double blind placebo controlled study to evaluate the effectiveness of purified d-Limonene as an agent to relieve the symptoms of indigestion and "heartburn"

Submission date 02/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/10/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

A randomised double blind placebo controlled study to evaluate the effectiveness of purified d-Limonene as an agent to relieve the symptoms of indigestion and "heartburn"

Study objectives

Small doses of purified d-Limonene (approximately 1000 mg) will ameliorate symptoms of indigestion and heartburn.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Members of the research team were affiliated with a University of Texas Medical Branch (UTMB) but WRC Labs has no affiliation with a university so approval from a University Institutional Review Board (IRB) could not be gained. Prior to initiating the study, an independent group from the university community was convened to review the study related to the three basic principles of ethics relevant to the protection of human subjects in research: respect for persons, beneficence and justice and they unanimously approved the study. Plans to seek University IRB approval will not be made unless a follow up study is performed.

Study design

Randomised double blind placebo controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gastrointestinal discomfort (indigestion/heartburn)

Interventions

Participants were randomised to ten (10) capsules of d-Limonene or placebo and instructed to take capsules orally and report symptom relief as instructed on provided questionnaire daily.

Capsules taken daily for ten days or every other day for twenty days for relief of symptoms of indigestion/heartburn.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Purified d-Limonene

Primary outcome(s)

Relief of symptoms as reported subjectively by study participants daily for twenty days. Participants rated their symptom relief on the original questionnaires to day 20.

Key secondary outcome(s)

Continued relief of symptoms after completing 10 capsules. A follow up questionnaire was sent out at the six month time-point for feedback on continued relief of symptoms.

Completion date

30/06/2001

Eligibility

Key inclusion criteria

Adults over 18 years of age who have experienced symptoms of indigestion and/or heartburn for at least six months.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Known sensitivity to citrus products or by products
2. Known sensitivity to soy bean oil
3. History of gastrointestinal bleeding or ulcers
4. Pregnancy

Date of first enrolment

01/09/2000

Date of final enrolment

30/06/2001

Locations

Countries of recruitment

United States of America

Study participating centre

13266 FM 362

Navasota

United States of America

77868

Sponsor information

Organisation

WRC Laboratories LP (USA)

Funder(s)

Funder type

Industry

Funder Name

WRC Laboratories LP (USA)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration