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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/08/2007	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Digestive System	

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
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

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
50

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)

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
WRC Laboratories LP (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration